

# WILLIAMS ♦ KHERKHER

DAVID W. ALEXANDER  
Attorney at Law

Direct 713-230-2343  
dalexander@williamskherkher.com

OF COUNSEL  
Ned Barnett  
Robert C. Kuehn

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Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: CITIZENS' PETITION PURSUANT TO 21 C. F. R. § 10.30 TO THE SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE COMMISSIONER OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION REQUESTING THAT:**

- (1) ***FOR CAUSE* INSPECTIONS BE CONDUCTED OF ALL FACILITIES WHERE MEDTRONIC SPRINT FIDELIS LEADS WERE MANUFACTURED; AND**
- (2) **PREMARKET APPROVAL FOR THE MEDTRONIC SPRINT FIDELIS LEADS BE WITHDRAWN RETROACTIVE TO SEPTEMBER 2004.**

Dear Sirs:

The undersigned Petitioners<sup>1</sup> hereby petition the United States Food and Drug Administration, pursuant to 21 U. S. C. §§ 360(h), 360e(e) and 393, and 21 C. F. R. § 10.30, to request the Commissioner of Food and Drugs to immediately conduct in-depth and comprehensive *For Cause* inspections of all facilities where Medtronic, Inc.'s, Sprint Fidelis Defibrillation Leads were designed, manufactured, sterilized and/or packaged. Petitioners also request that, depending on the *For Cause* inspection findings, the FDA withdraw the PMA of the Sprint Fidelis Leads and to make the withdrawal of the PMA retroactive to September 2004 if due process and the facts revealed in the inspections make such action appropriate.

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<sup>1</sup> See Petitioners Exhibit A.

Petitioners are individuals who were implanted with Medtronic, Inc.'s ("Medtronic") Sprint Fidelis Defibrillation Leads ("Fidelis Leads") between September 2004 to October 15, 2007. In the United States alone, 204,000 Fidelis Leads were implanted in patients, including Petitioners, and 166,500 remain implanted. The Fidelis Leads were recalled on October 15, 2007, due to defects which resulted in inappropriate and debilitating shocks or failure to deliver therapeutic shocks or pacing.

Petitioners have suffered a spectrum of injuries from their Fidelis Leads. For some, the lead has failed completely and has required a second, and sometimes third, surgery to remove or cap the defective Fidelis Lead and replace it with another defibrillation lead. For others, the defective Fidelis Lead has caused a series of debilitating shocks, but healthcare providers are reluctant to remove the lead due to the likelihood of surgical complications. For some of those who cannot undergo a second surgery, the defibrillation portion of their implantable cardioverter defibrillator ("ICD") has been disabled. They will not suffer repeated defibrillation shocks, but appropriate therapy is no longer available. For the majority, the Fidelis Lead has not yet inappropriately shocked them, but they live in constant fear of repeated 600-700 V shocks which they cannot stop or that therapy will not be delivered when needed.

The Fidelis Leads are Class III Medical Devices which undergo premarket approval evaluation by the FDA before they are allowed to be marketed.<sup>2</sup> If this be so, then Petitioners

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<sup>2</sup> <http://www.fda.gov/cdrh/devadvice/pma/printer.html>. Visited February 11, 2009. "Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. . . . PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe

wonder what went wrong with the Fidelis Leads. How could the FDA allow a Class III device to be marketed, which was later implanted in over 200,000 patients in the United States, causing death and countless injuries, and yet be on the market for only 36 months before recall? No one has provided any answers. For its part, Medtronic simply says, “[t]here are two primary locations where chronic conductor fractures have occurred on Sprint Fidelis leads: 1) the distal portion of the lead, affecting the anode (ring electrode) and 2) near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor.”<sup>3</sup> Medtronic also states that even with enhanced defect detection software, 51% of those with Fidelis Leads implanted will “receive less than two days advance notice or no notice” of lead failure – i.e., a series of life threatening shocks or no therapeutic shocks.<sup>4</sup> With some 166,500 U. S. citizens with Fidelis Leads still implanted, Petitioners find this unacceptable. Petitioners now turn to the FDA to assist them in finding answers to what happened and how to prevent it from happening again.

The answers to the questions about what led to the failure of the Fidelis Leads may well lie at Medtronic’s headquarters and Puerto Rican manufacturing facilities, where the leads were designed and manufactured. Was there a failure of quality systems? Were there systemic deviations from the PMA specifications during manufacture? Did Medtronic’s PMA application contain untrue statements of material fact which led the FDA to erroneously approve it?

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and effective for its intended use(s). . . .”

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<http://www.medtronic.com/crm/performance/downloads/mdt-prod-performance-2008-2-en.pdf>, at page 144. Visited February 11, 2009.

<sup>4</sup> *Id.*

The FDA visited at least one of Medtronic's Puerto Rican Fidelis Lead manufacturing sites in the period from October 29, 2007 to December 14, 2007.<sup>5</sup> One inspector was on site for 13 days to conduct PMA inspections for other products and, almost as an afterthought noted, that "additional coverage was provided to evaluate [the] voluntary class I recall . . . for Sprint Fidelis Leads."<sup>6</sup> The inspection was most likely a QSIT Level 1 with some additional coverage.<sup>7</sup> Petitioners find this level of inspection unacceptable.

The 204,000 U. S. citizens implanted with defective Fidelis Leads, and the 166,500 with leads still implanted, deserve a much more thorough inspection and investigation into the circumstances leading up to the recall. The inspection requested herein may yield information that is critical for these individuals' health and safety.

After the For Cause inspections Petitioners request here, the FDA may find answers to Petitioners' questions, and more, and conclude that the PMA should be withdrawn and, under appropriate circumstances, that the PMA withdrawal should be made retroactive to September 2004. In other words, the PMA for the Fidelis Leads should never have been granted in the first place.

#### **A. ACTION REQUESTED**

Under the mission of the FDA to protect human health as codified in 21 U. S. C. § 393<sup>8</sup> and

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<sup>5</sup> See Petitioners Exhibit B, Establishment Inspection Report, Medtronic Puerto Rico Operations Co., Villalba, PR 00766, FEI: 2649622, EI Start: 10/29/2007, EI End: 12/14/2007.

<sup>6</sup> *Id.* at pages 1 and 2.

<sup>7</sup> *Id.*

<sup>8</sup> The [FDA] shall – (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner; (2) with respect to such products, protect the public health by ensuring that – (C) there is

the authority granted by 21 U. S. C. § 360(h)<sup>9</sup>, Petitioners request that the FDA immediately conduct For Cause inspections of all facilities where the Fidelis Leads were designed, manufactured, sterilized and/or packaged. Petitioners also request that, depending on the For Cause inspection findings, the FDA withdraw the PMA of the Fidelis Leads under the authority granted to it by 21 U. S. C. § 360e(e)<sup>10</sup> and to make the withdrawal of the PMA retroactive to September 2004 if due process and the facts revealed in the inspections make such action appropriate.<sup>11</sup>

### **B. STATEMENT OF GROUNDS**

It is the mission of the FDA to protect human health by preventing the marketing of harmful medical devices. Among its many tools, the FDA accomplishes its mission through regular Abbreviated and Comprehensive inspections and more rigorous Compliance Follow-up and For Cause inspections when conditions warrant.<sup>12</sup> Petitioners assert here that the magnitude of the

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reasonable assurance of the safety and effectiveness of devices intended for human use. . . . 21 U. S. C. § 393.

<sup>9</sup> Every establishment in any State registered with the Secretary pursuant to this section shall be subject to inspection pursuant to 21 U. S. C. § 374 and every such establishment engaged in the manufacture, propagation, compounding, or processing of a . . . device . . . classified in . . . class . . . III shall be so inspected . . . at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter. 21 U. S. C. § 360(h).

<sup>10</sup> The Secretary shall . . . issue an order withdrawing approval of the application if the Secretary finds – (A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;. . . . 21 U. S. C. § 360e(e).

<sup>11</sup> The Secretary shall . . . issue an order withdrawing approval of the application if the Secretary finds – . . . (C) that the application contained or was accompanied by an untrue statement of a material fact;. . . . 21 U. S. C. § 360e(e).

<sup>12</sup> *See, e.g., Inspection of Medical Device Manufacturers*, Center for Devices and Radiological Health, issued June 15, 2006, Part III, pages 2.

adverse human health impact of the Fidelis Lead recall demands that For Cause inspections be performed. If the FDA takes the action requested here, injuries to those with Fidelis Leads still implanted will be reduced and lives may even be saved.

Between September 2004 and October 15, 2007, 204,000 U. S. citizens were implanted with Fidelis Leads and about 166,500 still have the leads implanted in them.<sup>13</sup> For the Model 6931 and 6949 leads, the failure rate is currently 5-6% at respectively 2 and 3.5 years after implant.<sup>14</sup> The failure rates for the Model 6931 and 6949 Leads are increasing at an alarming rate when compared to the failure rates for the Model 6944 and 6947 Leads.<sup>15</sup> At the current failure rates and the number of those with active Fidelis Leads, about 10,000 individuals will experience the failure of their Fidelis Lead within the next year.

Medtronic has published patient management recommendations for those with implanted Fidelis Leads.<sup>16</sup> However, these recommendations are made without the benefit of FDA's investigation into the circumstances surrounding the failure of the Fidelis Leads. If the FDA conducts For Cause inspections of Medtronic's Puerto Rican manufacturing facilities, causes of the failures of the Fidelis Leads will be revealed which are not currently known and impossible to become known through any other means. If the causes of the failures are discovered, appropriate

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<http://www.medtronic.com/crm/performance/downloads/mdt-prod-performance-2008-2-en.pdf>, at pages 80, 81, 86, 144. Visited February 11, 2009.

<sup>14</sup> *Id.* at pages 81, 86.

<sup>15</sup> *Id.* at pages 81, 84, 85, 86. The Model 6944 and 6947 Leads are those leads most closely resembling the Model 6931 and 6949 Leads, respectively.

<sup>16</sup> *Id.* at page 144.

patient management recommendations can be developed which will most certainly prevent unnecessary injuries and even save lives.

On June 8, 2004, FDA approved Medtronic's supplemental PMAs (S029 and S030) for the Fidelis Leads; the (1) 6930 (passive fixation, bipolar pace/sense, one coil); (2) 6931 (active fixation, bipolar pace/sense, one coil); (3) 6948 (passive fixation, bipolar pace/sense, two coils); and (4) 6949 (active fixation, bipolar pace/sense, two coils). After FDA approval, Medtronic began marketing the Fidelis Leads in September 2004 to replace its earlier Sprint Quattro Leads. The Fidelis Leads were smaller diameter than prior leads and this was attractive to electro-physiologists because they were easier to insert and less likely to obstruct blood flow.

Almost immediately after their introduction into the marketplace, reports began to emerge about failures of the Fidelis Leads.<sup>17</sup> Physicians at The Minneapolis Heart Institute also began noticing an abnormally high failure rate of the Fidelis Leads. In an effort to uncover the nature of the failures, The Minneapolis Heart Institute performed a study of the incidence of lead failures in the Fidelis Leads compared to Medtronic's Sprint Quattro Secure ("Quattro Secure") Leads.<sup>18</sup>

As reports of failures continued to mount, Medtronic issued a physician advisory on March 21, 2007, in the nature of a "Dear Healthcare Provider" letter, that advised physicians of "higher than expected conductor fracture rates in . . . Sprint Fidelis leads." In the face of an ever increasing number of serious injuries and deaths associated with the Fidelis Leads, the FDA finally compelled

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<sup>17</sup> See Petitioners Exhibit C, FDA MAUDE Database Search, first reported failure occurred October 30, 2004, a mere two months after the introduction of the Fidelis Leads on September 2, 2004.

<sup>18</sup> Hauser, et al., *Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead*, Heart Rhythm. 2007 Jul; 4(7): 892-6, Epub. 2007 Apr. 10.

Medtronic to announce a Class I Recall on October 15, 2007.

21 U. S. C. § 360(h) requires that every establishment engaged in the manufacture . . . of . . . a device . . . in . . . [C]lass . . . III shall be so inspected . . . at least once in the two-year period beginning with the date of registration . . . and at *least once in every successive two-year period thereafter*. Although at least one of Medtronic's facilities where the Fidelis Leads were manufactured has been inspected, it was not inspected with the rigor which is appropriate after a recall – i.e., a For Cause inspection.<sup>19</sup> In light of the magnitude of the human health tragedy caused by the Fidelis Leads, a QSIT Level 1 inspection performed apparently as an afterthought in October to December 2007 should not be counted as an inspection for purposes of 21 U. S. C. § 360(h). The appropriate level of inspection after the Fidelis Lead recall is a For Cause inspection.

The Fidelis Leads were manufactured at Medtronic's Puerto Rican subsidiaries. For Cause inspections of Medtronic's Puerto Rican facilities where the Fidelis Leads were manufactured will more likely than not reveal, among other things, numerous violations of 21 C. F. R. Part 803, Medical Device Reporting, Part 814, Premarket Approval of Medical Devices, and Part 820, Quality System Regulation. If violations of FDA regulations are found, as they most certainly will be, they may shed light on the nature of the failures of the Fidelis Leads.

After a recall, inspections of facilities which manufactured the recalled Class III Device may

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<sup>19</sup> See, e.g., *Inspection of Medical Device Manufacturers*, Center for Devices and Radiological Health, issued June 15, 2006: ***For Cause inspections are carried out in response to specific information that raises questions, concerns, or problems associated with a FDA regulated firm or commodity.*** . . . com[ing] to the attention of FDA from . . . ***Recall or market withdrawal.*** . . . Part III, pages 7-8 (emphasis added).

be performed on a “for cause” basis.<sup>20</sup> The scope of a For Cause inspection is dictated by the circumstances which have created the need for it.<sup>21</sup> For Cause inspections can be initiated at the request of FDA’s Center for Device and Radiological Health, Office of Regulatory Affairs, or Regional or District directives.<sup>22</sup> For Cause inspections are generally more in-depth than typical QSIT inspections.<sup>23</sup> After a recall, district offices of the FDA are encouraged to inspect Class III manufacturers on a priority basis.<sup>24</sup> For Cause inspections are focused towards specific quality problem(s), and attempt to trace the underlying cause, assuring that appropriate correction(s) and corrective action(s) are initiated.<sup>25</sup> It is just this kind of inspection that Petitioners believe will reveal what happened to create the human health debacle caused by the Fidelis Leads.

A For Cause inspection is not limited to the QSIT approach although it may adapt one or more of its inspection areas. A For Cause inspection may inspect all of the seven major quality systems within the Quality System regulations; including (1) Management Controls, (2) Design Controls, (3) Corrective and Preventive Actions (CAPA) (includes MDR, Corrections and Removals, and Tracking requirements), (4) Production and Process Controls (P&PC), (5) Facilities and

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<sup>20</sup> *Id.*

<sup>21</sup> *Id.* at Part III, page 2 (. . . For Cause inspections are dictated . . . by other regulatory information and may differ from the typical QSIT approach. . . ).

<sup>22</sup> *Id.* at Part III, page 8.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.* at Part II, page 3.

<sup>25</sup> *Id.*

Equipment Controls, (6) Materials Controls and (7) Document/Records/Change Controls.<sup>26</sup> Because a For Cause inspection is tailored to the circumstances, it can also cover conformity with 21 C. F. R. Part 814 (Premarket approval of Medical Devices).<sup>27</sup> Violations of 21 C. F. R. Part 814 may reveal systemic deviations from PMA specifications or one or more of the grounds under which the PMA for the Fidelis Leads may be withdrawn.<sup>28</sup>

Medtronic and its Puerto Rican subsidiaries have a long history of FDA Enforcement Activity dating from 1990 to the present.<sup>29</sup> Many of the FDA Enforcement Reports aimed at Medtronic's Puerto Rican manufacturing facilities involved recalls and/or voluntary withdrawals of implantable defibrillator devices and leads similar to the Fidelis Leads and which implicate numerous violations of FDA regulations and deviations from PMA requirements.<sup>30</sup>

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<sup>26</sup> *Id.* at Part III, page 3.

<sup>27</sup> *Id.* at Part I, page 1 (For medical devices, the routine compliance program inspects and enforces activities related to Quality Systems (21 C. F. R. Part 820), Medical Device Reporting (MDR) (21 C. F. R. Part 803), Medical Device Tracking (21 C. F. R. Part 821), Corrections and Removals (21 C. F. R. Part 806), and Registration and Listing (21 C. F. R. Part 807)); *see also* Part III, page 8 (. . . [For Cause] inspections are generally more in-depth in particular areas than typical QSIT inspections.).

<sup>28</sup> *See, e.g.*, 21 C. F. R. § 814.46.

<sup>29</sup> *See e.g.*, [http://google2.fda.gov/search?access=p&entq=0&getfields=\\* &sa=Go&output=xml\\_no\\_dtd&sort=date%3AD%3AL%3Ad1&ie=UTF-8&lr=&client=FDA&q=Medtronic&ud=1&site=enforcement\\_report&oe=UTF-8&proxystylesheet=FDA&ip=67.66.217.82&filter=0](http://google2.fda.gov/search?access=p&entq=0&getfields=* &sa=Go&output=xml_no_dtd&sort=date%3AD%3AL%3Ad1&ie=UTF-8&lr=&client=FDA&q=Medtronic&ud=1&site=enforcement_report&oe=UTF-8&proxystylesheet=FDA&ip=67.66.217.82&filter=0). Visited June 9, 2008 (list of 208 weekly FDA Enforcement Reports from 1990 to the present directed to Medtronic, Inc., and its subsidiary companies and manufacturing facilities).

<sup>30</sup> *See* <http://www.fda.gov/bbs/topics/ENFORCE/ENF00006.html>. Visited June 2, 2008 (July 23, 1991 FDA Enforcement Report – Medtronic 7005, 7005C, 7006, and 7008 Implantable Pacemakers have anomalous performance resulting in potential loss of sensing and output which violates, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70,

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Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);  
<http://www.fda.gov/bbs/topics/ENFORCE/ENF00126.html>. Visited May 26, 2008 (February 5, 1992 FDA Enforcement Report – Medtronic Capsure 5025 Pacing Lead improperly labeled violating, among other FDA regulations, 21 C. F. R. 820.120, Device Labeling);  
<http://www.fda.gov/bbs/topics/ENFORCE/ENF00308.html>. Visited June 2, 2008 (April 13, 1994 FDA Enforcement Report – Medtronic Model 4004, 4004M, 4082 Pacing Leads fail at a rate greater than anticipated in violation of, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);  
<http://www.fda.gov/bbs/topics/ENFORCE/ENF00312.html>. Visited May 30, 2008 (May 11, 1994 FDA Enforcement Report – Medtronic Model 7084 Pacemaker distributed without Premarket Approval violating the regulations in 21 C. F. R. Part 814, Premarket Approval of Medical Devices);  
<http://www.fda.gov/bbs/topics/ENFORCE/ENF00365.html>. Visited May 30, 2008 (February 15, 1995 FDA Enforcement Report – Medtronic Capsure SP 5524M-53CM Pacing Lead mislabeled in violation of, among other FDA regulations, 21 C. F. R. 820.120, Device Labeling);  
<http://www.fda.gov/bbs/topics/ENFORCE/ENF00459.html>. Visited May 30, 2008 (November 13, 1996 FDA Enforcement Report – Medtronic Capsure 4504, 4504M, and 4582 Pacing Leads fail sooner than expected due to insulation degradation which violates, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);  
<http://www.fda.gov/bbs/topics/ENFORCE/ENF00478.html>. Visited May 26, 2008 (March 26, 1997 FDA Enforcement Report – Medtronic Thera Implantable Pacemaker Models and Jewel Defibrillator recalled due to manufacturing defects in integrated circuitry which implicates violations of, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);  
<http://www.fda.gov/bbs/topics/ENFORCE/ENF00483.html>. Visited June 2, 2008 (April 30, 1997 FDA Enforcement Report – Medtronic Jewel 7221Cx Implantable Defibrillators were distributed with connector header blocks which were out-of-specification resulting in device failure which violates, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);  
<http://www.fda.gov/bbs/topics/ENFORCE/ENF00589.html>. Visited May 30, 2008 (May 12, 1999 FDA Enforcement Report – Medtronic GEM 7227 and 7227Cx Implantable Defibrillators recalled due to abnormally high current drain causing premature battery depletion violating, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);

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<http://www.fda.gov/bbs/topics/ENFORCE/ENF00620.html>. Visited May 30, 2008 (December 15, 1999 FDA Enforcement Report – Medtronic GEM 7226Cx and 7229Cx Implantable Defibrillators recalled due to improper P+ wire routing and adhesive application in violation of, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);

<http://www.fda.gov/bbs/topics/ENFORCE/ENF00629.html>. Visited May 26, 2008 (February 16, 2000 FDA Enforcement Report – Medtronic Jewel II 7223Cx and GEM DR 7271 Implantable Defibrillators recalled due to extended charge times for high voltage capacitors which violates, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);

<http://www.fda.gov/bbs/topics/ENFORCE/ENF00635.html>. Visited May 26, 2008 (March 29, 2000 FDA Enforcement Report – Medtronic GEM II VR and GEM II DR Implantable Defibrillator recalled due to fracture of soldered connection which could result in loss of device output violating, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);

<http://www.fda.gov/bbs/topics/ENFORCE/2001/ENF00704.html>. Visited May 26, 2008 (August 1, 2001 FDA Enforcement Report – Medtronic Micro Jewel II 7223Cx Implantable Defibrillator recalled due to extended charge times which delays the delivery of cardioversion or defibrillation which violates, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);

<http://www.fda.gov/bbs/topics/ENFORCE/2001/ENF00718.html>. Visited June 2, 2008 (November 7, 2001 FDA Enforcement Report – Medtronic 7425 Implantable Pulse Generator shocks the patient at the implant site due to missing battery insulation violating, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);

<http://www.fda.gov/bbs/topics/ENFORCE/2006/ENF00936.html>. Visited June 2, 2008 (January 25, 2006 FDA Enforcement Report – Medtronic Deep Brain Stimulation System labeling provided an incorrect maximum MRI head specific absorption rate which violates, among other FDA regulations, 21 C. F. R. 820.120, Device Labeling);

<http://www.fda.gov/bbs/topics/ENFORCE/2006/ENF00955.html>. Visited May 30, 2008 (June 7, 2006 FDA Enforcement Report – Medtronic Kinetra 7428 Neurostimulator for Deep Brain Stimulation may fail due to lifted wire bonds between the circuitry and battery violating, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance);

<http://www.fda.gov/bbs/topics/ENFORCE/2006/ENF00984.html>. Visited June 2, 2008

Although inspections have been conducted of at least one of Medtronic's Fidelis Lead manufacturing facilities, they have apparently not been performed with the detail appropriate to a facility with Puerto Rico's enforcement history. Other Medtronic facilities have also been involved in the design of the Fidelis Leads. Even though inspections of the Puerto Rican manufacturing sites may have been performed every two years as required by 21 U. S. C. § 360(h), they must have been very superficial to result in the enforcement history which we see today.

A report on a superficial FDA inspection may be found in the Establishment Inspection Report for the 10/29/2007 to 12/14/2007 inspection of at least one of Medtronic's Fidelis Lead manufacturing sites.<sup>31</sup> Astonishingly Medtronic's employees admitted that manufacturing techniques contributed to the Fidelis Lead failures – “Mr. Murillo and Mr. Ganion indicated that manufacturing process has been ruled as one possible cause of the fracture failures.”<sup>32</sup> This is evidence of a faulty PMA submission (the manufacturing process submitted for approval was never intended to be implemented) or deviations from PMA specifications (technicians routinely deviated from the

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(December 27, 2006 FDA Enforcement Report – expansion of recall of Medtronic Kinetra 7428 Neurostimulator); <http://www.fda.gov/bbs/topics/ENFORCE/2007/ENF01009.html>. Visited May 26, 2008 (June 20, 2007 FDA Enforcement Report – Medtronic DBS Lead Kit 3389S-40 labeled with erroneous model number violating, among other FDA regulations, 21 C. F. R. 820.120, Device Labeling); <http://www.fda.gov/bbs/topics/ENFORCE/2007/ENF01028.html>. Visited May 26, 2008 (October 31, 2007 FDA Enforcement Report – Medtronic Model 6930, 6931, 6948 and 6949 Sprint Fidelis Leads recalled due to lead fractures which implicate violations of, among other FDA regulations, 21 C. F. R. 820.30, Design Controls; 21 C. F. R. 820.70, Production and Process Controls; 21 C. F. R. 820.75, Process Validation; 21 C. F. R. 820.80, Receiving, In-Process, and Finished Device Acceptance).

<sup>31</sup> See Petitioners Exhibit B.

<sup>32</sup> *Id.* at page 15.

approved process). In spite of this admission and *that conductor fracture failures were the reason for the recall*, the FDA inspector reviewed just six Product Review Requests (“PRR”) related to lead resistance and intermittency failures.<sup>33</sup>

The inspector spent the majority of his inspection and reporting on Fidelis Lead sterilization.<sup>34</sup> The Fidelis Lead recall was due to conductor fractures, not improper sterilization techniques. The inspector also noted that, “[a]t the time of the closing of this inspection, an FDA investigation was still in progress at Medtronic headquarters in Minneapolis, MN.”<sup>35</sup> The report is silent on the QSIT Level of the inspection that was being performed at Medtronic’s Minneapolis headquarters.

This supports Petitioners’ view that For Cause inspections of all Medtronic facilities involved in the Fidelis Leads are warranted based; (1) on the failure of the inspector to focus his inspection on the circumstances surrounding the recall and, (2) that other inspections of unknown QSIT Level have been conducted or are underway at other facilities. Further, Medtronic had not disposed of its recalled finished and unfinished Fidelis Lead inventory because it was waiting until “all FDA inspections are finished.”<sup>36</sup> A For Cause inspection is not only warranted, Medtronic’s Puerto Rican facility is apparently expecting it will be conducted.

FDA inspections of Medtronic’s facilities are apparently not being performed with the rigor

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<sup>33</sup> *Id.* at page 16.

<sup>34</sup> *Id.* at pages 16-21.

<sup>35</sup> *Id.* at page 14.

<sup>36</sup> *Id.* at page 16.

appropriate to the health risks of its devices. According to information publicly available, the last Warning Letter directed at Medtronic is dated October 1, 2007.<sup>37</sup> In light of the numerous FDA Enforcement Actions against Medtronic's Puerto Rican manufacturing facilities, scarcity of Warning Letters against Medtronic, and the superficial inspection conducted after the Fidelis Lead recall, it is abundantly clear to Petitioners that the inspections contemplated by 21 U. S. C. § 360(h) are not being performed in a manner and frequency sufficient to protect human health.

Through FDA's failure to conduct the requested inspections at the appropriate level of inquiry, Petitioners have been unable to determine how the Fidelis Leads, which apparently received "rigorous" scrutiny before approval and were to be manufactured according to FDA regulations, failed so quickly and injured so many in the 3 short years they were on the market. Petitioners have a right to know whether or not Medtronic complied with all FDA regulations in obtaining PMA approval for the Fidelis Leads and in their manufacture, including, without limitation, 21 C. F. R. Parts 803 (Medical Device Reporting), 814 (Premarket Approval of Medical Devices) and 820 (Quality System Regulation). FDA's failure to conduct appropriately detailed inspections as required by 21 U. S. C. § 360(h) impairs Petitioners' ability to learn how they could be implanted with a faulty medical device. Without the requested For Cause inspections, Petitioners will never know the adequacy of FDA's approval process or the manufacturing practices, process and regulatory compliance of Medtronic with respect to its Fidelis Leads.

Selected Medtronic Annual Reports regarding PMA 920015 indicate that various

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<sup>37</sup> See Petitioners Exhibit D.

modifications of the Fidelis Leads were attempted, all without success, to correct deficiencies.<sup>38</sup> Some of these implicate violations of 21 C. F. R. Part 814 (Premarket approval of Medical Devices). For example, within the second year of introduction of the Fidelis Leads, Medtronic's Twelfth Annual Report (December 10, 2005 to December 31, 2006) shows a change made under 21 C. F. R. § 814.39(b) (no PMA supplement required) to the crimping process.<sup>39</sup> A change from 4 to 8 indents in the contact area between the connector pin and connector pin cap affected the continuity (impedance or resistance) between these elements.<sup>40</sup> This is one of the areas where failures were noted.<sup>41</sup> Petitioners assert that any change in the area of a failure related to the recall of the Fidelis Leads should be the subject of a For Cause inspection. A For Cause inspection may reveal that Medtronic violated 21 C. F. R. § 814.39(a) by making a change in the manufacturing process which affected safety and effectiveness without first seeking approval of a PMA supplement.<sup>42</sup>

In the reporting year December 31, 2006, to September 30, 2007, several modifications were again made to the Fidelis Leads in the areas of failures and without PMA supplements. The post

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<sup>38</sup> See Petitioners Exhibit E, Medtronic's P920015 Reports for the Periods December 10, 2005 to December 31, 2006 and December 31, 2006 to September 30, 2007.

<sup>39</sup> *Id.* at Twelfth Annual Report, page 6.

<sup>40</sup> *Id.*

<sup>41</sup> See Petitioners Exhibit F, PMA Annual Report Review, PMA Number: P920015/R013, page 8 (DF-1 Cable fractures within RV or SVC *connector legs*) (emphasis added).

<sup>42</sup> After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA *before making a change affecting the safety or effectiveness of the device* for which the applicant has an approved PMA. . . . 21 C. F. R. § 814.39(a) (emphasis added).

cure process of the DF-1 connector insulation and outer coil welding procedures were changed.<sup>43</sup> Changes in the post cure process of the DF-1 connector are related to fractures in this area.<sup>44</sup> The outer coil welding process is also implicated in the failures of the Fidelis Leads.<sup>45</sup> These changes were again made under 21 C. F. R. § 814.39(b) without PMA supplements although they are related to the safety and effectiveness of the Fidelis Leads. A For Cause inspection focused on these changes may reveal that Medtronic violated 21 C. F. R. § 814.39(a) by making a change in the manufacturing process which affected safety and effectiveness without a PMA supplement.

Depending on the results of the For Cause inspections, Petitioners also request that the FDA withdraw the PMA of the Medtronic's Fidelis Leads. If the PMA is withdrawn, the Fidelis Leads will not be allowed to be reintroduced to the marketplace as they are currently designed or with merely minor supplemental changes. Withdrawal of a PMA is authorized whenever the Secretary finds that the "device is unsafe or ineffective under the conditions use prescribed, recommended or suggested in the labeling."<sup>46</sup> The FDA has already determined that the Fidelis Leads have a "reasonable probability to cause serious adverse health consequences, including death."<sup>47</sup>

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<sup>43</sup> See Petitioners Exhibit E, Annual Report for P920015, for the period December 31, 2006, to September 30, 2007, dated December 7, 2007, pages 8-10, 11-13.

<sup>44</sup> See FN41 (*DF-1 Cable fractures* within RV or SVC connector legs) (emphasis added).

<sup>45</sup> See FN41 (*Coil fractures* within 5 CM of the end of the anchor sleeve; DF-1 Cable fractures proximal of proximal *RV coil*/cross groove) (emphasis added).

<sup>46</sup> See *supra* FN10.

<sup>47</sup> See Petitioners Exhibit G, letter from FDA to William A. Hawkins, President, Medtronic, Inc., dated November 1, 2007.

Further support for the withdrawal of the PMA might also be found by inappropriate actions by FDA managers overseeing the Fidelis Lead approval process. The FDA's Center for Devices and Radiological Health ("CDRH") has the responsibility of approving PMAs for medical devices.<sup>48</sup> The CDRH's medical device approval process has apparently been corrupted which sometimes allows dangerous devices to be marketed – i.e., like the Fidelis Leads. On October 14, 2008, a group of concerned FDA physicians and scientists from the Office of Device Evaluation wrote an urgent letter to United States Congressional Representative John D. Dingell.<sup>49</sup> In the letter, the physicians and scientists sought Mr. Dingell's immediate "intervention because serious misconduct by managers of the . . . FDA at the . . . CDRH is interfering with our responsibility to ensure the safety and effectiveness of medical devices for the American public. . . ."<sup>50</sup> The physicians and scientists were concerned that managers routinely approve devices using flawed methods, evidence and conclusions and fail to reevaluate potentially unsafe device already on the market.<sup>51</sup> They went on to say that "managers at CDRH have deviated from FDA's mission to identify and address underlying problems with medical devices before they cause irreparable harm, and this deviation has placed the American people at risk."<sup>52</sup> If these allegations are true, the health and safety of 204,000 U. S. citizens

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<sup>48</sup> See, e.g., <http://www.fda.gov/cdrh/devadvice/3122.html>. Getting To Market With A Medical Device. Visited February 16, 2009.

<sup>49</sup> See Petitioners Exhibit H, letter from FDA physicians and scientists to United States Congressional Representative John D. Dingell, dated October 14, 2008.

<sup>50</sup> *Id.* at page 1.

<sup>51</sup> *Id.* at page 3.

<sup>52</sup> *Id.* at page 4.

implanted with defective Fidelis Leads may have been put at risk by the actions of managers in the CDRH.

Petitioners admit that For Cause inspections are generally aimed at regulated entities, like Medtronic, not the FDA itself. However, there is nothing to prevent the FDA from expanding the scope of a For Cause inspection to encompass its own actions which resulted in the approval of the PMAs for the faulty Fidelis Leads. For Cause inspections may have whatever scope is appropriate under the circumstances. They are focused towards identifying specific quality problem(s), and attempt to trace the underlying causes of a recall, assuring that appropriate correction(s) and corrective action(s) are initiated.<sup>53</sup> A For Cause inspection of appropriate scope may reveal that CDRH managers inappropriately overruled more circumspect physicians and scientists in the PMA approval process for the Fidelis Leads.

There is sufficient support for immediate withdrawal of the PMA. Medtronic's own request for a voluntary recall confirms that it regarded its Fidelis Leads as violating the law.<sup>54</sup> The labeling for the Fidelis Leads was never changed from September 2004 to October 15, 2007.<sup>55</sup> Further,

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<sup>53</sup> See, e.g., *Inspection of Medical Device Manufacturers*, Center for Devices and Radiological Health, issued June 15, 2006: ***For Cause inspections are carried out in response to specific information that raises questions, concerns, or problems associated with a FDA regulated firm or commodity.*** . . . com[ing] to the attention of FDA from . . . ***Recall or market withdrawal.*** . . . Part III, pages 7-8 (emphasis added); see also Part III, page 2 (. . . For Cause inspections are dictated . . . by other regulatory information and may differ from the typical QSIT approach. . . ).

<sup>54</sup> See 21 C. F. R. § 7.46 (stating that a firm removes a product from the market because it believes it to be violative of federal law).

<sup>55</sup> See Petitioners Exhibit I, FDA Premarket Approval Database, PMA No. 920015, PMA Supplements which apply to the Fidelis leads - S029, S030, S032, S037, and S038 – printed from the FDA web-site on February 20, 2008 and May 14, 2008.

although some modifications were made to the Fidelis Leads with and without PMA supplements and FDA approval, none materially affected their fundamental weaknesses – coil and conductor fractures.<sup>56</sup> In other words, the Fidelis Leads were “unsafe or ineffective under the conditions of use prescribed, recommended or suggested in the labeling” from September 2004 to October 15, 2007 – the entire period they were manufactured and sold by Medtronic.

Depending on the facts revealed in the requested For Cause inspections, Petitioners further request that the FDA consider making the withdrawal of the PMA for the Fidelis Leads retroactive to September 2004. The FDA may also withdraw the PMA for Fidelis Leads if it determines that Medtronic failed to “maintain records. . . or has not complied with the requirements of 21 U. S. C § 360” throughout their marketing, or that Medtronic’s “[PMA] application contained or was accompanied by an untrue statement of a material fact.”<sup>57</sup> Agency decision-making may have retroactive effect as long as the fundamental requirement of due process is not violated.<sup>58</sup> In the inspections requested by Petitioners, the FDA will most certainly learn that the Fidelis Leads were “unsafe or ineffective under the conditions of use prescribed, recommended or suggested in the labeling” and Medtronic failed to “maintain records. . . or has not complied with the requirements of 21 U. S. C. § 360” from September 2004 to October 15, 2007 and that Medtronic’s “[PMA]

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<sup>56</sup> *Id.*

<sup>57</sup> 21 U. S. C. § 360e.

<sup>58</sup> *NLRB v. Guy F. Atkinson Co.*, 195 F.2d 141, 148-149 (9th Cir. 1952) (Courts, in making ad hoc adjudications, regularly apply rules and doctrines not previously announced, to prior conduct of the parties. . . We assume that an adjudication by an administrative board is likewise not limited to prospective operation only by any fundamental requirement of due process.).

application contained or was accompanied by an untrue statement of a material fact.” It is for these reasons Petitioners request that the FDA consider withdrawing the PMA of the Fidelis Leads and making the withdrawal retroactive to September 2004.

The lives of some 204,000 U. S. citizens were adversely affected by the introduction and marketing of the Fidelis Leads. Some have died, some have had to undergo additional surgeries to replace the defective leads and others live with the constant fear of repeated 600-700 V debilitating shocks that they themselves cannot stop. Petitioners bring this petition to the FDA for themselves and the 166,500 U. S. citizens who still have the Fidelis Lead implanted in them and the 10,000 who will experience lead failure within the next year. It is for these reasons, Petitioners request that:

- a. under the FDA’s mission codified in 21 U. S. C. § 393 and the authority granted to it by 21 U. S. C. § 360(h), that the FDA immediately conduct For Cause inspections of all facilities where the Fidelis Leads were designed, manufactured, sterilized and/or packaged;
- b. depending on the For Cause inspection findings, the FDA withdraw the PMA of the Fidelis Leads under the authority granted to it by 21 U. S. C. § 360e(e); and
- c. to make the withdrawal of the PMA retroactive to September 2004 if due process and the facts revealed in the inspections make such action appropriate.

### C. ENVIRONMENTAL IMPACT

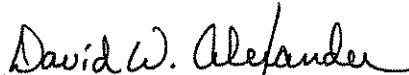
Petitioners claim a categorical exclusion from an environmental assessment or environmental impact statement under 21 C. F. R. §§ 25.30 and 25.34.

**D. ECONOMIC IMPACT**

Petitioners are not required to provide data regarding the economic impact of the request unless required by the Commissioner.<sup>59</sup>

**E. CERTIFICATION**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



David W. Alexander  
Texas Bar No. 24029417  
USDC SDTX Bar No. 32900  
John T. Boundas  
Texas Bar No. 00793367  
USDC SDTX Bar No. 25155  
James L. Doyle II  
Texas Bar No. 06094450  
USDC SDTX Bar No. 10576  
**WILLIAMS KHERKHER HART BOUNDAS, LLP**  
8441 Gulf Freeway, Ste. 600  
Houston, Texas 77017  
Telephone: (713) 230-2200  
Facsimile: (713) 643-6226

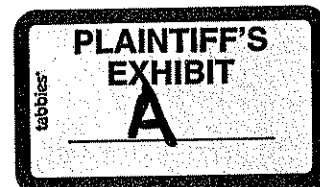
**ATTORNEYS FOR PETITIONERS**

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<sup>59</sup> 21 C. F. R. § 10.30.

MEDTRONIC Citizen Petitioners

Petitioner's Name
Ali, Jubal
Allums, Paul C.
Alred, Carl Lee
Anderson, Guthrie E.
Anglemier, Eric S.
Archibald, Joseph
Baker, Arthur Edward
Barnes, Charles Wayne
Barnes, Hurd L.
Beard, Billy Gene, Sr.
Boles, Bruce
Bonin, Ronnie, Sr.
Brewer, James E.
Brinkman, Richard Wayne, Sr.
Brooks, Jamie Leo
Broussard, Gustave, Jr.
Brown, James Lewis
Burnette, Bonnie Lee
Burress, Doyle T.
Busby, Martha M.
Campbell, Jimmy
Campbell, Wenda
Cannon, Denver Clinton
Cannon, Ira Walter
Cantu, Peter S., Jr. (deceased)
Carroll, Harry T., Jr.
Carter, Tommy L. (deceased)
Chappell, Yvonne
Conley, Mary Gay
Cooper, Henry C., Jr.
Curtis, Melinda Lee
Davidson, Stanley L. (deceased)
Davis, Fay Darlene
DeForest, Kenneth Dale
Deitz, Rickey L.
Demkiw, Omelian (deceased)
Dobson, Jack D.
Donaldson, Delano Arnold
Donaldson, Marilyn
Drahman, James E.
Dunn, Danny D.
Dutton, Randall Gene
Ellis, Travis M.
Embry, Danny Edward



MEDTRONIC Citizen Petitioners

Petitioner's Name
Evans, Robert L.
Fanning, Oscar Lewis
Fisher, Isaac Manuel, Sr. (deceased)
Franklin, Carolyn Marie
Fuller, Robert James (deceased)
Garner, Carlton L.
Gedra, Frank (deceased)
Gorbett, Richard H.
Gover, Elizabeth Ann
Gray, Charles Eugene (deceased)
Greene, Bobby R.
Guidry, Jerome Carl
Gunn, Joe C.
Hale, Novella S.
Hammonds, Gordon W., Sr.
Harlow, Clyde W.
Harrington, Charlotte Ann
Harris, Mattie S.
Hicks, Rickey Greg
Hollis, Marvin E.
Holton, Lathon, Jr.
Hopkins, Anna Marie
Hudgins, Howard G. (deceased)
Hudson, Reginald Vaughan
Hughes, Timothy Charles
Hunt, Nancy J.
Hunter, Sharon Elizabeth
Hurst, Larry Dale (deceased)
Jackson, Donald Larry
Jackson, Paul Derek
Johnson, Artia B.
Johnson, Larry Allen
Jones, Margaret P. (deceased)
Jones, Robert B.
Jordan, George
Keeton, Marcus, Jr.
Kirby, Hal Vaughndell
Kline, Floyd H.
Kontowski, Jr., Felix
Lang, Malcolm
Laviolette, Glynn Paul
Lear, Charles E.
Lee, James (deceased)
Lewis, Silas, Jr.

MEDTRONIC Citizen Petitioners

Petitioner's Name
Ludiker, Billy Dean (deceased)
Lynch, Jimmie D.
Marcus, Jack (deceased)
Mariani, Richard F.
Martin, Paul D.
Martin, William R.
Mathews, Donald Ray (deceased)
Mayer, Myron Robert
McBroom, Marilyn J.
McCloud, Johnny
McDowell, Bobby Gene (deceased)
McFarland, Charlie, Jr.
McKinney, Mary L.
McMillan, Jerry
Millsap, Lester D. (deceased)
Mitchell, Sarano J.
Mongogna, Anthony
Morris, James
Mosley, Frederick March
Nazario, Sergio E.
Neely, Phillip E.
Newton, Brenda Ann
Noe, Arnold Eugene, Sr.
Ogea, Frank (deceased)
Oney, Beulah F.
Paulus, Gary W.
Payne, Andrea M.
Payne, Hal White
Pittman, Betty Lou
Poe, Charles E.
Prater, Orville
Price, Howard
Ragan, David Allen
Randolph, Lewis D.
Reed, Ella Rene
Reed, Phebie
Reeves, Shirley A.
Rosso, James T.
Rothschild, James Derell
Roy, Noel Armand
Ruby, Bobby Dale (deceased)
Sanchez, Schlender Nolan
Sanders, Jimmy B.
Scott, Dorothy M.

MEDTRONIC Citizen Petitioners

Petitioner's Name
Shadd, Bonnie Jean
Shavers, Loyed Ray
Shelton, Betty L.
Silvia, Manuel, Jr. (deceased)
Skoczylas, Edward (deceased)
Smith, Catherine
Smith, Chester V., Jr.
Smith, Clyde Wayne
Smith, Kenneth O'Neal
Snyder, Robert S.
Spikes, Mary Jane
Sprayberry, James L.
Steele, Joe, III
Stein, Annette O.
Sumpter, Phalia L.
Sykes, Edna M.
Tapia, Joaquin (deceased)
Thompson, Joseph Michael
Thornton, Steven G.
Tolbert, Johnny E.
Vancel, Lee Roy
Wade, Bethel
Wayne, Carl G.
Whitehead, Gary W.
Wilson, Dallas Martin (deceased)
Wilson, William Earl (deceased)
Woodward, Daniel Roy
Wright, Lorenzo Lee
Zerniak, Stanley J.

**Establishment Inspection Report**  
Medtronic Puerto Rico Operations Co.  
Villalba, PR. 00766

FEI: 2649622  
EI Start: 10/29/2007  
EI End: 12/14/2007

## SUMMARY

Inspection of this manufacturer of cardiac pacing leads, spinal cord stimulation systems, and cardiac electrophysiology catheters (medical devices) was conducted as part of SJN-DO FY'08 work plan and as a request from CDRH to conduct a PMA inspection for product P060039 (Medtronic Attain StarFix model 4195 lead) under assignment ID 891086 and a Post-market inspection for product P970004/S33 (InterStim Sacral Nerve Stimulator). Coverage was followed in accordance with CP 7383.001 "Medical Device Premarket and Postmarket Inspections", and CP 7382.845 "Inspection of Medical Device Manufacturers". In addition, a QSIT Level 1 (abbreviated) inspection was conducted which covered the CAPA (corrective and preventive actions) and P & PC (production and process controls) subsystems. Additional coverage was provided to evaluate voluntary class I recall Z-0067-2008 for Sprint Fidelis Leads.

Previous surveillance, Post-PMA and PMA inspection dated 3/9/06 was classified NAI and disclosed no objectionable conditions. No form FDA-483, Inspectional Observations, was issued and PMA P970004/S33 was recommended for approval.

Current inspection disclosed no significance deviations from the QSR. Two observations, which were not included in a form FDA-483, were discussed with the firm's management. These are: (1) not all the equipments involved in an out-of-specifications sterilization non-conformance were included within the scope of the corrective and preventive actions implemented; and (2) written procedure for non-conformance analysis and report is not clear as for the timeframe to log, open and/or initiate an investigation for sterilization failures after any given defect is noticed and reported as a non-conformance. Corrections were promised by the plant manager. No form FDA-483, Inspectional Observations, was issued. Inspection of PMA P060039 (Medtronic Attain StarFix model 4195 lead) found no objectionable conditions. Approval recommendation was send to SJN-DO pre-approval manager (PAM).

No refusals were encountered and no samples were collected during the inspection.

## ADMINISTRATIVE DATA

Inspected firm: Medtronic Puerto Rico Operations Co.  
Location: Carr # 149 Km 56.3  
Villalba, PR 00766  
Phone: 787-847-3500  
FAX:  
Mailing address: P.O. Box 6001



**Establishment Inspection Report**  
Medtronic Puerto Rico Operations Co.  
Villalba, PR 00766

FEI: 2649622  
EI Start: 10/29/2007  
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Villalba, PR 00766

Dates of inspection: 10/29/2007, 10/30/2007, 10/31/2007, 11/1/2007, 11/2/2007,  
11/28/2007, 11/29/2007, 12/5/2007, 12/6/2007, 12/7/2007,  
12/12/2007, 12/13/2007, 12/14/2007

Days in the facility: 13

Participants: Hector J Colon Torres, Investigator

## HISTORY

History of this firm remains as reported during previous inspection. Medtronic Puerto Rico Operations Co. (MPROC), located in Villalba, PR, is comprised of Medtronic Cardiac Rhythm Management (CRDM) and Medtronic Neuromodulation (Neuro and Gastro/Urology) businesses. The firm manufactures cardiac pacing leads, spinal cord stimulation systems, and cardiac electrophysiology catheters (please refer to **Exhibit #1, pages 1-2**, for a list of product families manufactured at MPROC Villalba). All the products manufactured at the Villalba plant are sterilized on-site by ethylene oxide (EtO), except for the diagnostic catheters which are sterilized by gamma radiation at (b) (4) and the urology (b) (4) products which are sterilized by EtO at (b) (4) in (b) (4). Medtronic Villalba is part of MPROC which also comprise the Juncos, PR and Humacao, PR facilities. However, each site has its own and independent Quality System.

MPROC Villalba most responsible individual is Mr. Gerardo Mari-Roca, Sr. Manufacturing Director/Plant Manager. Mr. Mari-Roca reports directly to MPROC Vice President, Mr. Manuel Santiago, who in turn reports to Mr. Brian Urke, VP CRDM Operations. **Exhibit #2, pages 1-5** includes the current organization structure for both MPROC Villalba CRDM & Neuro, and corporate.

Any official correspondence from the Agency to MPROC Villalba should be addressed to:

Medtronic Puerto Rico Operations Co.  
Attn: Mr. Gerardo Mari-Roca, Plant manager  
Rd. 149, Km. 56.3  
Call Box 6001  
Villalba, PR 00766

**Establishment Inspection Report**  
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This firm is currently registered with FDA for 2007 under number 2649622. Please refer to **Exhibit #3, pages 1-2**, for copies of the annual registration submission dated 1/10/2007.

## INTERSTATE COMMERCE

All the products manufactured at Medtronic Villalba are shipped to several distribution centers located throughout United States, Europe, and Asia. The main distribution centers are Heerlen, Netherlands, EOC Dist in Netherlands; Moundsview, MN, East Distributor in Minneapolis, MN; and San Juan, PR, Medtronic Sales Office in PR. In addition, most major components used for the manufacture of finished products come from external sources in interstate commerce.

## JURISDICTION

The products manufactured at Medtronic Villalba are medical devices intended for human use. In addition, the finished devices are shipped to the United States, Europe, and Asia, though entering in interstate movement. **Exhibit #1** is a list of product families manufactured by this firm.

## INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

On 10/29/07, I met, presented my credentials, and issued a form FDA-482; Notice of Inspection, to Mr. Gerardo Mari-Roca, who identified himself as the Sr. Manufacturing Director CRDM/Plant Manager of Medtronic Puerto Rico Operations Co., located at Villalba, PR. Mr. Mari-Roca's authority was evidenced as described on the firm's Quality Manual. He also accepted the forms FDA-482; Notice of Inspection (on 10/29/07 and 11/28/07), and expressed his commitment for the voluntary corrections of the verbal observations issued during the inspection. I also observed several official documents signed by him throughout the inspection to include memorandums and notifications posted at bulletin boards.

I also met and presented my credentials to Mrs. Betsy Rosario Rivera, Sr. QA/QS Manager and Medtronic Villalba Management Representative. In addition to Mrs. Rosario I met Mr. Rafael Berly-Torres, Regulatory Compliance Manager, Mr. Miguel O. Beltrán-Delgado, Sr. QA/QS Manager for MPROC Neuromodulation business, Mr. Ricardo J. Lugo, Sr. Manufacturing Director

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for MPROC Neuromodulation, and Mr. Norman Ganion, Sr. Principal Auditor (Minneapolis, MN). Mrs. Rosario, Mr. Berly, Mr. Ganion and Mr. Beltrán accompanied me throughout the inspection.

The following people were also interviewed and provided valuable information and support during the inspection:

- Mr. Norberto Rivera, Sr. Manufacturing Engineer – He explained the manufacturing process for the Medtronic Attain StarFix model 4195 lead (4195 lead).
- Mr. Roberto Murillo, QA/QS Manager – He provided information in reference to trends, non-conformances, and investigations. He also explained the Product Transfer process for the 4195 lead.
- Mrs. Wanda Alvarez, Principal Engineer – She explained the activities related to Left Heart 4195 transfer implementation, and Blue Push Tubing components qualification and visual inspection.
- Mrs. Eileen Ruiz, Laboratory Supervisor – She provided information in reference to the activities conducted at MPROC for the sterilization of the 4195 lead to include loading patterns, bioburden, endotoxin, and EtO residual testing. In addition, she explained sterilization records and charts.
- Mrs. Mayte Acevedo, Sr. Quality Engineer – She explained the activities related to CAPA 000806.
- Mr. Craig Meadows, CRDM Engineering Services Manager – He provided information in reference to sterilization.
- Mr. Erick Cuvillier, Clinical Research Director Latin America – He explained the implanting process and functioning of leads to both right and left sides of the heart.
- Mr. José Muñoz, Sr. Quality Assurance Engineer – Provided requested copies of labeling.
- Mr. Joe Dupay, Sr. Program Director – Provided information about the 4195 OUS events.
- Mrs. Vicki Bjorklund, Designer – She provided information related to designing and functional aspects of the 4195 lead.
- Mr. James Roche, Reliability Engineer – He provided information about the validated lobe deployment test, clinical studies, and statistical rationale for the acceptability of the test.

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Medtronic Puerto Rico Operations Co.  
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EI Start: 10/29/2007  
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- Mr. Miguel Galarza, Quality Engineer Sterilization and Catheters – He explained sterilization issues, DPM's and investigations.
- Mrs. María Vega, Quality Control Engineer Sterilization and Final Pack – She explained the defect of "damage strain relief" on the 3830 model.
- Mrs. Gisela González, Sr. Quality Engineer, Neuromodulation – She provided information related to non-conformance investigation 07NR.042 and all related events.
- Mr. Alexis Tomassini, Manufacturing Engineer Sterilization (CRDM) – He provided information in reference to the sterilization chambers, preventive maintenance and calibration.
- Mrs. Diane Wolf, Complaint Handling Manager (Minneapolis, MN) – She provided information related to complaint reports and acronyms.
- Mrs. Iris Hernández, Sr. Manufacturing Engineer – She provided information related to the manufacturing flow of the sprint fidelis lead and the fracture defect.

#### **FIRM'S TRAINING PROGRAM**

This area was not evaluated in detail during this inspection. However, during the review of corrective and preventive actions documents it was evident that a training program is implemented as some of the corrective actions that I reviewed include training given to employees.

#### **MANUFACTURING/DESIGN OPERATIONS**

The product subject to this PMA inspection was the P060039 (Medtronic Attain StarFix model 4195 lead). I did a tour of the room where the 4195 lead is manufactured. Mr. Norberto Rivera explained in detail all manufacturing steps. The manufacturing steps for the 4195 lead are described in Exhibit #4, flowchart of Manufacturing Document Procedure document no. 502992-JIT, titled "4195 Lead Assembly". Design operations are conducted at the Minneapolis, MN facility of Medtronic.

**Establishment Inspection Report**  
Medtronic Puerto Rico Operations Co.  
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## COMPLAINTS

The complaints information was evaluated throughout the inspection. Samples of complaints were requested and reviewed for the evaluation of the CAPA subsystem, the PMA, and the Post-PMA portions of the inspection. Please refer to the "CAPA", "PMA", and "Post-PMA" headings of this report for details.

## CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)

The CAPA subsystem was evaluated as part of a QSIT Level I (Abbreviated) inspection. I requested the firm's CAPA procedures for review and found that the requirements of the quality system regulation are defined and documented. The firm identifies and analyses several sources of product and quality problems such as consumer complaints, product non-conformances, distributors' quality feedback, and internal audits among others. Upon questioning and reviewing of documents, the firm showed me that the quality data is analyzed, trends are identified and if needed CAPA's are generated and implemented. The firm uses statistical techniques such as pareto charts, spread sheets, and other non-statistical techniques for data analysis. This analysis includes comparisons between data sources to establish global view of quality problems. I also requested and reviewed several written procedures related to the firm's Quality System and Quality Data Analysis (complaints, NCR's, PRR's, etc.) during the inspection.

I challenged the quality data information system by selecting several quality data sources: MDR's, NCR's (non-conformance report/investigations), consumer complaints, PRR's (Product Review Request) and process deviations. I requested a listing in electronic format of all the events from the selected sources from April 2006 through October 2007. I used the table #2 of the *Binomial Staged Sampling Plans, Row "A", Column "0 out of"* to select a (b) (4) record sample for each source. MDR activities are conducted at the headquarters located in Minneapolis, MN. In addition, I requested a total of (b) (4) GCAPA's (global CAPA's) generated and implemented since April 2006, thus increasing the sample to (b) (4) investigation records. No objectionable conditions were found.

In addition, and as part of the CAPA subsystem inspection I requested and reviewed the trending reports for all three Medtronic business (CRDM, Neuro, and Catheters) from October 2007 and going back one year.

For the sterilization level DPM (defects per million) summary, I requested the 3:1 chart for May-Sep 07; the major offenders leading to high DPM's on each of those months; and the equivalent of defect units in relation to the DPM value.

I also requested:

- NCR 07NR.074
- OCT 2007 Trend Report for cell no. 211 (Select Secure 3830 model)

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I reviewed the Oct 2007 (FY 08) MPROC CRDM DPM Trend Report dated 11/12/07. A negative trend is observed on sterilization level DPM's from May-Oct 2007 for the Select Secure 3830 model in which the major contributors are "collapse accessory cavity" and "stain in outer tray". I also reviewed NCR 07NR.012 in reference to mix-up units in sterilization chambers.

Mr. Galarza explained the two defects leading to high DPM's in sterilization. He added that both defects are cosmetic and that there is no impact to the quality and functionality of the product. He showed an actual example of each defect. Product is repacked and re-sterilized. NCR 07NR.074 was opened for the investigation of the collapse defect. Corrective and preventive actions were implemented in the inner tray design. Defects reported after the implemented actions are statistically non-significant compared to the expected values as per CAPA 000179.

Mr. Murillo explained the defects related to the Select Secure 3830 model that caused a DPM increase from May-Oct 2007 (b) (4) Mrs. Maria Vega explained the defect of "damage strain relief" on the 3830 model.

The evaluation of this subsystem (CAPA) resulted in the discussion of two verbal observations which are discussed in more detail in the "Objectionable Conditions and Management Response" section of this report.

## PRODUCTION AND PROCESS CONTROLS

I choose the manufacturing process of the Attain Starfix™ 4195 for the evaluation of this subsystem. This product is also the subject for the PMA part of this inspection. I evaluated the process transfer, equipment qualifications, process validations, component qualifications, non-conformances investigations, sterilization, and training of personnel. Please refer to the "PMA Evaluation" section of this report for details.

## PMA EVALUATION

The product subject to this PMA P060039 inspection was the Medtronic Attain StarFix model 4195 lead. The model 4195 is a (b) (4)

(b) (4) This lead features deployable lobes for stable fixation.

On 10/29/07, I did a tour of the room where the 4195 lead is manufactured. Mr. Norberto Rivera explained in detail all manufacturing steps. I also requested the following documentation:

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- Manufacturing Flowchart
- Volume of product manufactured so far for OUS (non-US markets) and since when.
- Separate complaints list for the 4195 model.
- Distribution for the 4195 in OUS.
- Product Transfer SOP
- Implementation Plan/Report
- List of trained employees
- Process Validation Plan/Report

The general qualification and validation requirements for MPROC Villalba are detailed and defined in written SOP (b) (4). The validation requirements, as defined in Exhibit #5 are, in chronological order, the Installation Qualification, Operational Qualification, Process Qualification, and Process Validation.

I reviewed Procedure (b) (4) titled "Product/Process/Technology Introduction" (Exhibit #6) to include the implementation plan and report, documents no. (b) (4) and (b) (4) (Exhibits #7 and #8). (b) (6) explained the activities for the Process Validation Plan and Report. She indicated that the 4195 lead is designed to be used with any left heart device. (b) (6) explained all the activities related to the transfer of the product from Rice Creek, MN to the Villalba, PR facility. The Transfer Implementation Phase 1 Report (Exhibit #8) dated "10 JUL 06", indicates that "after completion of the activities related to the Training, Qualification Builds, Validation Builds, and Special Processes Validations at MPROC for lead model 4195, the manufacturing process (b) (4) Exhibit #9, titled 4195 Lead assembly) is considered qualified and can be released to production". It also indicates that the "4195 Interfacility Transfer Implementation Phase 1 is considered completed". This report also enumerates a series of manufacturing issues that occurred during the process of implementation. I informed to those present that I would require clarification on those issues during the course of the inspection as I request its pertinent documentation.

I requested and reviewed the plan and report titled "Process Qualification for Lead Model 4195 Transferred to MPROC Facility" (Please refer to Exhibits #10 and #11). The report dated "03 AUG 05" indicates in the conclusion section that "although the results taken from the qualification activities performed during the (b) (4) operational at MPRI showed that all units met the manufacturing processes requirement for the lead model 4195, a lead failing the reliability test (b) (4) made this process-qualification failed". I requested the information in reference to the failing test.

Mr. Berly provided document no. (b) (4) titled "Product Spec - Lead, Cardiac Vein, Unipolar, Curved, Over-The-Wire, Deployable Lobes" (Exhibit #12). Section (b) (4) of the document describes the lobe deployment requirements (Exhibit #12, page 6). The (b) (4) is a reliability test conducted at Medtronic, Inc. Minneapolis, MN, to verify that the lobes can meet the (b) (4) requirements. The test requirements indicate (b) (4) the (b) (4) and (b) (4) (note: the firm uses this word to describe the return of the lobes to their original position before deployment) when positioned in a left heart path model

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(b) (4) or (b) (4) equivalent using the following method". It also indicates that "the lead shall not be damaged after (b) (4) of full deployment and undeployment within the (b) (4) (approximately (b) (4) of the left heart path model (b) (4) or (b) (4). This test was only conducted for qualification/validation purposes and it is not a finished product release criteria. Mr. Murillo indicated that in the manufacturing side there is indeed a (b) (4) required for product release. He indicated that the manufacturing (b) (4) is applied to all leads manufactured (100%) and consist in the (b) (4) and (b) (4). This functionality is visually confirmed by the operator in charge of conducting the test (please refer to Exhibit #9, page 19).

The firm identified the root cause of the failure as "lack of adhesive over the indicator rings". The investigation, corrective and preventive actions are documented on non-conformance report (b) (4) Exhibit #13). Mr. Miguel A. Galarza explained the document and provided the evidence for the corrective actions.

I requested and reviewed the documents no. (b) (4) and (b) (4) titled "Process (b) (4) (b) (4) plan/report for lead model 4195 transferred to MPROC facility" (Exhibits #14 and #15). After all pertinent activities were finished, the report concludes that "based on the results of the qualification and reliability testing activities performed for the lead model 4195, the manufacturing process 502992-JIT is considered qualified at MPROC facility".

I requested and reviewed the documents no. (b) (4) and (b) (4) titled, "Process Validation Plan/Report for 4195 Lead Model -MPROC Facility" (Exhibits #16 and #17). The report indicates that on "Lot (b) (4) of the (b) (4) failed the (b) (4). The lead samples did not deploy in the tortuous path model". In addition, the report concludes that (b) (4) lots will have to repeat all of the validation testing and a third lot with corrective measures in place will have to repeat the (b) (4) to meet the validation (b) (4) requirement". This is the same test that failed during the process qualification activities.

I requested the following:

- (b) (4) plan and report.
- All related information and reports in reference to the validation failures and the (b) (4) vendor corrective actions and process (b) (4).
- CAPA's and NCR's related to the 4195 model.

The firm found that engineering analysis of passed and failed validation test samples showed the deployment failures were related to non-uniformity in the coating along the length of the push tubing in the failed samples compared to uniform coating on passed samples, as stated by (b) (6) (b) (6) in her memo dated (b) (4) and titled (b) (4) (b) (4) (Exhibit #18). This document number (b) (4) was created upon my request on (b) (4) as an aid to (b) (4) issue and all related activities. This document indicates the problem extension, background, root cause, corrective and preventive actions, risk assessment, and conclusions.

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As a result of this finding, a corrective action was implemented at the inspection level of the component at the supplier (Medtronic Energy and Component Center – MECC) facility in Rice Creek, MN. I reviewed document number (b) (4) titled "Inspection of (b) (4) Coated Tubing" (Exhibit #19). This document explains in detail all the inspectional steps for the tubing component which will be further used in the manufacture of the 4195 lead at MPROC, Villalba.

I requested and reviewed documents number (b) (4) and (b) (4) titled "Process (b) (4) (b) (4) Plan/Report for 4195 Lead Model – MPROC Facility" (Exhibit #20 and #21). When the firm found that the root cause of the (b) (4) failures was at the component level, a (b) (4) of the process was performed at the manufacturing level in MPROC, Villalba. The (b) (4) (b) (4) report indicates that "based on the validation results, the 4195 lead model assembly process is considered validated at MPROC manufacturing facility". In addition, it indicates that "further qualification of the addition of the visual inspection control measure for the blue push tubing will be completed per the test plan (b) (4)". This is in reference to the qualification conducted for the verification of the corrective action recommended and implemented at the vendor (MECC).

I requested and reviewed documents number (b) (4) and (b) (4) titled "Qualification Plan/Report for Visual Inspection for Push Tubing Coating – Model 4195" (Exhibit #22 and #23). After all the activities were conducted the report concludes that "the addition of the visual inspection method is not qualified based on the failure to meet the acceptance requirements for (b) (4) cycles and required (b) (4) sets". In addition, the report mentions that "in the case of qualification run (b) (4) of the (b) (4) failed the lobe deployment test. For qualification run (b) (4) of the (b) (4) samples did not pass the lobe deployment test. In some instances, the lead sample did not meet the requirement that all (b) (4) must (b) (4). For other samples, (b) (4) (b) (4) occurred, but failed to meet the (b) (4). This was the third time the samples failed to pass the (b) (4) even after corrective actions were implemented.

I requested the following:

- Investigation reports from rice creek (Medtronic Energy and Component Center – MECC) internal supplier addressing the failures, root cause and corrective and preventive actions implemented.
- Product specifications (Doc. No. (b) (4) revisions effective at the moment of both validation failures.

The push tubing vendor investigated the coating process (reference document no. (b) (4) (b) (4) please refer to Exhibit #24) and through an iterative process described in the project plan, improved the uniformity of the push tubing coating. The compilation of the process adjustments was re-qualified and validated at the component level at the vendor (reference document no. (b) (4) – Process Qualification of (b) (4)

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and (b) (4) - 4195 Plan, Exhibit #25, and document no. (b) (4) - 4195 (b) (4) and (b) (4) Qualification Report - Overall Length Feature, Exhibit #26/ document no. (b) (4) Process Qualification of (b) (4) and (b) (4) - 4195 Report, Exhibit #27). The tubing manufactured with the revalidated manufacturing process was subsequently qualified in the final assembly configuration to confirm that the vendor process improvements successfully resolved the functional requirement for lobe deployment on (b) (4) (reference document no. (b) (4) tubing component qualification report). I reviewed Doc. No. (b) (4) (b) (4) (b) (4) (b) (6) explained the document and indicated that it explains the root cause of the failure and the activities set as deliverables and exception for the project.

I requested and reviewed the (b) (4) documents no. (b) (4) and (b) (4) Exhibits #28 and #29). (b) (6) explained the activities related to these documents. The report indicates that "based on the component qualification results, the (b) (4) component from the updated component manufacturing process is considered qualified for use on the 4195 lead model". The report also indicates that "all samples passed the (b) (4) requirement. Leads passed the requirement with no anomalies noted during the testing. No additional anomalies were seen on the samples after the (b) (4) (b) (4)

After reviewing these reports I asked (b) (6) and all those present to explain why the (b) (4) (b) (4) requirement was changed from (b) (4) of (b) (4) and (b) (4) (b) (4). I indicated that during the qualification/validation activities, the lobe deployment test failed three times with a requirement of (b) (4) and then passed when the requirement was reduced to (b) (4) (b) (4). I requested copy of the product specifications version at the time of the qualifications/validation. I reviewed the 4195 product specifications, revisions G (Exhibit #30) and H (Exhibit #31). A change in the lobe deployment requirements was implemented between both revisions. Revision (b) (4) section (b) (4) indicates (b) (4) of (b) (4) and (b) (4) while Revision (b) (4) section (b) (4) indicates (b) (4). This test was the one that failed in the process validation and then in the (b) (4) qualification after corrective actions were implemented. I requested a written justification explaining the change of the test specifications/requirements from (b) (4)

I also requested the following:

- Indications for use (labeling) for the 4195 lead.
- Specifics about the (b) (4) reliability testing to include the conditions under which the test is performed.
- Specifics in terms of corrective and preventive actions as well as health risk assessment for the particular failure of (b) (4) and (b) (4)

I evaluated three NCR's (non-conformance investigations), one CAPA and several (b) (4) US consumer complaints, referred by the firm as "events". I reviewed NCR's no. (b) (4) (b) (4) and (b) (4) Mrs. Mayte Acevedo, Sr. Quality Engineer explained the activities

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related to CAPA 000806. In addition, from the (b) (4) complaint list I selected a total of (b) (4) "events" for review. The events numbers are: I (b) (4) for device ID (b) (4) for ID (b) (4) (b) (4) and (b) (4). All the selected events are associated to lobe deployment issues and are from already OUS marketed devices or from US clinical studies.

Mr. Jose Muñoz provided a copy of the Attain Starfix™ 4195 directions manual (Exhibit #32). The directions for use section of this manual (section 6, pages 8-17) do not indicate a maximum for deployment/undeployment of the lobes of the lead when implanted or relocated. He added that the directions for use for the subject PMA will be similar to those on the OUS product.

Mr. Ganion provided a copy of document number (b) (4) titled "FMEA for Lead Model 4195" (Exhibit #33). This document shows the Failure Modes and Effects Analysis for the 4195 model. Product FMEA demonstrates high RPN's for each failure mode referencing (b) (4) or (b) (4).

I expressed my concerns with the effectiveness of the corrective actions. I indicated to all present that "events" related to problems with the deployment/undeployment keep reporting for the already distributed 4195 OUS leads. In addition, the directions for use are not clear in terms of how many times or cycles could be applied to (b) (4) the (b) (4) of the lead when implanted and/or relocated. Mr. Ganion indicated that a component characterization project was conducted to support the final component qualification and process validation. He provided copies of document number (b) (4) titled (b) (4) (b) (4) (Exhibit #34) and number (b) (4) titled (b) (4) (b) (4) (Exhibit #35).

Mr. James Roche provided, via e-mail, the specifics about the lobe deployment reliability testing to include the conditions under which the test is performed (please refer to Exhibit #36).

In reference to the complaints or "events" Mr. Ganion indicated that all product returns are reported as events even if the device was not used. He mentioned that sometimes the whole system is returned and all components of the system are also reported within the event complaint. Mr. Joe Dupay explained that the OUS events for the 4195 lead in reference to (b) (4) are not related to the blue tubing coating which was the main corrective action implemented during process validation. He mentioned that the returns and deployment events have been decreasing and none have been reported since 5/07. He indicated that the OUS experiences have show the importance of good physician training. He added that for the US lead there will be a mandatory training for representatives prior to receiving the product for sale and a required physician training that will be completed prior to a first implant. Mr. Dupay provided a written summary of "experiences" on 4195 (b) (4). In this report he explains the reported events, the no relation between the events and the coating issues, and the next steps for US release. He concludes that "there is no data to suggest that the field experiences seen to date (up-to-date) are related to the original coating

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validation issues" and that "the corrective actions and subsequent passing validation appears effective". (Please refer to Exhibit #37).

In terms of the justification to change the lobe deployment test requirements from (b) (4) (b) (4) Mr. James Roche indicated that there is a (b) (4) of probability that a Physician will not exceed (b) (4). This was determined by clinical studies that showed that the mean for the number of times the (b) (4) were (b) (4) for each unique model 4195 lead was (b) (4). Based on the mean plus (b) (4) standard deviations the (b) (4) cycles was calculated and set to (b) (4). He added, in reference to my concern about the directions for use, that due to the high probability for the physicians to (b) (4) of (b) (4) during an implant and/or relocation of the lead, there is no need to indicate a maximum number in the directions for use of this product. Mr. Roche provided a written rationale describing the above (Exhibit #38).

#### Sterilization

I requested the following:

- Sterilization activities and related documentation for the 4195 model.
- Specifics on the equivalency of sterilization for Qualification processes at Rice Creek vs Villalba plus equivalency between the 4195 and the 4193 model that was used as comparison.

I reviewed the Microbial Qualification for lead model 4195 manufactured at Medtronic Villalba Plan/Report (b) (4). I also requested and reviewed the Sterilization Qualification Protocol and Report for the 4195 (Rice Creek). Mr. Craig Meadows and Mrs. Eileen Ruiz explained the justification in reference to the similarities between the 4195 model and other leads. They also showed the evidence in reference to the worst case lead processed at the Villalba facility and how the 4195 falls into the same procedure. They indicated that all CDRM leads are sterilized under the same procedure and parameters.

I also reviewed procedure no (b) (4), titled (b) (4) of product for (b) (4). Mrs. Ruiz explained the activities to include loading patterns for the 4195. I also reviewed the Sterilization Certification Report (b) (4) Doc. No. (b) (4) which show all the loading configurations and aeration times for all CDRM lead products. No significant objectionable conditions were observed.

#### **POSTMARKET EVALUATION**

The product subject to this Post-PMA inspection was the P970004/S33 InterStim® Sacral Nerve Stimulator (a system comprised of various finished devices working together). Medtronic Villalba is

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engaged in the manufacture of the leads (finished device) used in this system. Other finished devices used together as part of this system are manufactured at the Juncos, PR plant.

As part of the evaluation of the subject product, I requested and reviewed the following documents:

- List of consumer complaints since PMA approval.
- Manufacturing and sales volumes since approval.
- List of changes since approval.
- List of qualifications/validations since approval.
- Copies of all protocols and reports for qualifications/validations for models 3093 and 3889 since approval.
- For manufacturing process no. (b) (4) copy of versions (b) (4) and (b) (4) For no. (b) (4) (b) (4) copy of versions (b) (4) and (b) (4)

I reviewed the documentation for the process/document changes implemented since approval. I also reviewed the Qualifications/Validations No. (b) (4) and (b) (4) for laser equipment (b) (4) and (b) (4) for laser equipment (b) (4) and Master Validation Plan/Report no. (b) (4) and (b) (4) for equipments relocation.

I selected a total of 15 PCR's (Product Comment Report - complaints for Neuromodulation business) from the list of consumer complaints since the PMA approval. The PCR numbers are: (b) (4) (b) (4) (b) (4) and (b) (4)

I also requested one set of labeling for both models being evaluated for Post-PMA, P97004/S33 (Exhibit #39). Mr. Beltran provided all the documentation I requested. No objectionable conditions were observed upon evaluation of post market activities and data for the InterStim® Sacral Nerve Stimulator model.

## RECALL PROCEDURES

During this inspection I covered Class I recall Z-0067-2008 for Sprint Fidelis Leads. The firm found lead breaks (fractures) resulting in inappropriate shocks and hence loss of adequate therapy. This product was subject to a voluntary recall initiated by the firm on 10/7/07. At the time of the closing of this inspection, an FDA investigation was still in progress at Medtronic headquarters in Minneapolis, MN.

This product has four different models: 6930, 6931, 6948, and 6949. The manufacturing of these lead began about 3-4 years ago. The 6949 is the lead with the highest sales volume and it is also the model with the highest number of reported complaints. The chronic conductor fracture was

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identified by Medtronic headquarters to be the cause of the failures which triggered the product recall.

I requested the following:

- Process flow chart (for the 6949 model, Exhibit #40).
- List of PRR's related to fractures/test failures.
- Trend report for defect related to fracture in Fidelis models since two years ago.
- Description of all four conductors for the 6949 and 6948 models (for the 6930 and 6931 models, three conductors only)
- List of SCAR's (Supplier Corrective Action Request) for conductors used in Fidelis models

(b) (6) explained the manufacturing process and the fracture defect. She indicated that the Fidelis models are smaller in diameter than other leads manufactured at the Villalba plant. She also indicated that the (b) (4) and (b) (4) cables are unique to the Fidelis family. Mr. Murillo indicated that all leads are 100% tested for resistance and intermittency. He added that these tests will capture any defects on the leads that might be caused by fractures.

Complaints are handled at a corporate level in Minneapolis, MN. MPROC, Villalba receives for investigation only those deemed to be related to manufacturing issues but have access to all within the (b) (4) database. Upon receipt, an (b) (4) (b) (4) is generated. There has been no (b) (4) generated related to fractures in Fidelis. Mr. Murillo and Mr. Ganion indicated that manufacturing process has been ruled as one possible cause of the fracture failures.

The raw material, supplier audits, and supplier corrective actions and investigations are handled by a group/department called SQA (Supplier Quality Assurance). This group is mainly located at the MPROC Juncos facility but their work extends to all three MPROC facilities in Puerto Rico (Juncos, Villalba, and Humacao). The group is composed by a SQA Director, Sr. QA's and inspectors (Juncos facility only).

(b) (6) provided a list of components used in the manufacture of Fidelis models. All part numbers are unique to the Fidelis family except for part no. (b) (4) which is the sense cable (b) (4). This cable is also used by the (b) (4) models. The Fidelis models are a new generation of the (b) (4).

Only (b) (4) have been generated. Both are not manufacturing related but instead for mix-up problems. I requested and reviewed (b) (4) and (b) (4). No deficiencies were noted.

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MPROC Villalba discontinued the manufacturing and distribution of the Sprint Fidelis leads when Medtronic headquarters decided to voluntarily recall the leads. LPHO (Local Product Hold Order) no. (b) (4) (Exhibit #41) was generated and (b) (4) finished units were placed in SPNFG (Stop Processing Notice Finished Good). In addition, several components at the assembly level were also placed on hold (Exhibit #42). The final disposition for these products will be scrap.

I requested and reviewed the following six PRR's related to resistance and intermittency failures involving Fidelis models: V012059, V005766, V008084, V008114, V008223, and V008642. Mr. Murillo explained the documents. No objectionable conditions were observed.

I also requested for review non-conformance report no. (b) (4). Mr. Murillo explained the PRR's, defect trend reports and (b) (4). He mentioned that the defect was related to the crimping of the cross groove and the tooling in use. He added that the problem was causing high resistance. He also mentioned that it is not related to fracture problems leading to recall Fidelis, which ruled out as being manufacturing related. I reviewed the trend reports showing resistance and intermittency defects as major contributors for high DPM's. All of them were addressed on (b) (4) (b) (4).

Mr. Murillo explained that fractures are caused mostly by mishandling of the leads by the physicians during implant. He indicated that during the process they inspect 100% for resistance and intermittency, 100% verification of crimp indentations, and pull strength sample test.

I visited the room where all the Fidelis (both finished and unfinished) models are stored awaiting disposition. All products are already in scrap status in the system. Mrs. Rosario and Mr. Ganion indicated that the "how" and "when" of the final disposition is not yet determined and that the decision will come from headquarters and firm lawyers when all FDA inspections are finished.

I also reviewed CAPA 000778 which is related to contamination of raw material. I also reviewed (b) (4) which is related to damage inner coil and was deemed as an isolated event due to operator technique. Finally, I reviewed (b) (4) which is related to training and qualification activities. No objectionable conditions were observed.

#### **OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

The following verbal observations were discussed with firm's management during the inspection:

- 1- Not all the equipments involved in an out-of-specifications sterilization non-conformance were included within the scope of the corrective and preventive actions implemented.

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During the evaluation of nonconformance report number (b) (4) (Exhibit #43) and all pertinent documentation, I noticed that corrective and preventive actions were not implemented to all sterilizers involved in the incidents.

On 12/6/07, I requested and reviewed nonconformance report (b) (4). The "final report" version was dated (b) (4). The report was originally opened for the investigation of an incident dated 9/20/06 and described as "ETO gas concentration was lower than specifications at the end of the exposure phase". Since then, four more incidents involving seven more lots have happened and are summarized in the following table. A Product Review Request or PRR was generated as per written procedures for each of the five incidents as showed in the table below. Please refer to Exhibits #44, # 45, # 46, # 47, # 48, #49, and #50, for copies of the PRR's mentioned below.

Incident Date	PRR No.	Lot No.	Model	Quantity Affected	Sterilizer /Sterilizer Lot No.	Actual Value EtO Conc. (mg/l)	Specification Eto Conc.(mg/l)
1) 9/20/06	V000230	V012545	3387S-40	47	45 / V6263453	<b>(b) (4)</b>	<b>(4)</b>
2) 11/28/06	0634468V	J0664512V	5076-52	73	22 / V6326224		
3) 12/28/06	V000580	V017927	3998-28	39	44 / V6362442		
4) 1/24/07	V001295	V019424	3888-33	44	39 / V7024392		
	V001296	V019449	3887-33				
	V001297	V019739	3387-28				
5) 4/25/07	V004791	V032588	3387-40	27	39 / 7115393		

During my review of related documentation, I noticed that lot no. V032588 from incident #5 was initially found out-of-specifications for EtO concentration (Exhibit #51, "Process Inspection Checklist For (b) (4) but upon further reevaluation of the sterilization chart (which is the official record of choice) the lot was found within parameters. However, (b) (4) includes a second lot no. V032336. This lot was found to be OOS with an actual value of (b) (4). (b) (4) This lot is not mentioned within the investigation documentation (b) (4).

I requested for review all the evidence related to the OOS and the disposition for all eight lots involved. PRR's for each indicates that lots from incidents (b) (4) were (b) (4) and lots from incident (b) (4) were disposed as (b) (4).

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(b) (6) clarified that sterilization lot number V7115391 corresponds to lot V03233 only. She mentioned that lot no. V032637 documented on the sterilization process record is a "monitor" number assigned by the system (b) (4) which is part of the routing process of the device. (b) (6) indicated that a monitor number is automatically assigned to a lot when other activities, such as reviews, testing, etc., are pending and the manufacturing process shall continue. Please refer to **Exhibit #52**, for copy of the "Sterilization and Aeration Process Record" for lot no. V7115391, which indicates that lot no. V032637 was rejected due to "ETO gas concentration out of specifications".

(b) (6) indicated that for incident #5 the lots identified on the PRR were disposed as (b) (4) after investigation showed that all parameters were met and that the problem was identified as to be the sensor which was found out of tolerance (OOT). I requested and reviewed the documentation in reference to the OOT (**Exhibit #53**) and the rationale used in the calculations that indicates that the lots involved were indeed within specification (**Exhibit #54**). The sensor (b) (4) was found out of specifications and it was calibrated on 4/27/07 (**Exhibit #55**).

The (b) (4) was logged on (b) (4). The initial report dated (b) (4) assesses the incident occurred on (b) (4). The ETO sensor was calibrated as corrective action. The product was re-sterilized. An update to the NCR was documented on (b) (4) (**Exhibit #56**). This update added the incidents (b) (4) and (b) (4) to the investigation.

During the evaluation of nonconformance report number (b) (4) (**Exhibit #43**) and all pertinent documentation, I noticed that corrective and preventive actions were not implemented to all sterilizers involved in the incidents as follows:

- 1- Another update was documented on (b) (4) (**Exhibit #57**). This update identified new corrective actions since previous ones were not effective. One of the corrective actions was "ETO sensors calibration files for sterilizer (b) (4) will be checked to investigate calibration results". This action only identified sterilizer (b) (4). Other sterilizers involved (b) (4) were not included in the corrective action. In addition, preventive actions were not identified for sterilizers not showing the problem but performing the same process. Mr. Murillo and Mr. Ganion indicated that sterilizer (b) (4) was tagged because it was involved in incident (b) (4) and the sensor was "suspected" to be out of tolerance. They added that the sensor of sterilizer (b) (4) was indeed found OOT and that was the reason for the corrective action to be specific for that sensor only. I verified the dates and found that sensor from sterilizer (b) (4) was found OOT on 4/26/07 (**Exhibit #53, and #55**), which is seven days after the corrective action was identified (4/19/07).

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2- Following update was dated (b) (4) and documented as "Final Report" (Exhibit #58). Additional corrective actions were recommended. Actions taken to identify root cause include "evaluate ETO sensors historical data to evaluate if calibration time frame can be challenge". This action was completed on (b) (4) (Exhibit #59) in which an evaluation was conducted at technical services files for sterilizers: (b) (4) (b) (4) and (b) (4). Mr. Berly provided a table showing all sterilizers at MPROC with its corresponding MPR number (Exhibit #60). The sterilizers included in the evaluation were (b) (4) and (b) (4). These sterilizers belong to the (b) (4) business. The sterilizers from CDRM were not included within the scope of this action taken.

Another update dated (b) (4) was also documented as "Final Report" (Exhibit #61). ETO sensors calibration timeframe and ETO cartridges were identified as possible root causes of this discrepancy. However, Mr. Beltran indicated that the real root cause have not been identified yet. For that reason a characterization study is being performed in order to test if the EtO cartridges that weight less than 152 grams comply with the net weight requirements range of (b) (4) (Exhibit #62).

(b) (6) Mr. Berly, and Mr. Ganion acknowledge the observation. Mr. Berly indicated that the Non-Conformance procedure has been updated and improved some time ago. He added that the current version will be updated to be clearer and to reflect changes based on the inspectional observations. Mr. Ganion agreed and added that any detail or concern expressed during the inspection will be considered for further improvements in any pertinent area or procedure.

On 12/14/07, during the inspection closeout, Mr. Berly provided a copy of a draft version for the updated Non-Conformance Analysis and Report written procedure (Exhibit #63) and added that more changes will be added. I indicated that any corrections will be verified during the next inspection.

2- ~~Written procedure for non-conformance analysis and report is not clear as for the timeframe to log, open and/or initiate an investigation for sterilization failures after any given defect is noticed and reported as a non-conformance.~~

On 12/7/07, during the evaluation of the documentation pertinent to the five sterilization incidents referenced on non-conformance report (b) (4) (please refer to previous observation), I noticed a deviation from written procedures and procedures unclear. The incident #2 reported on 11/22/06 (Exhibit #45) and rejected on 11/28/06 was not "logged" until 1/10/07 as non-conformance report (b) (4) (Exhibit #64).

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Written procedure no. (b) (4) titled Non-Conformance Analysis and Report (Exhibit #65), indicates on section (b) (4) that "for all sterilization failures that require PRB activity, an investigation and report will be issued". This investigation and report is a non-conformance report or NCR. A PRB is a "designed area to evaluate PRR", and a PRR is a "product review request", which is an initial assessment of a non-conformance by a designated person or group. An NCR is a higher level tool for investigations of non-conformances.

An NCR follows a PRR if the incident needs to be escalated for a more complete and detailed investigation. Written procedure no. (b) (4) titled "Handling of Nonconforming Product" (Exhibit #66), indicates on section 1.1 that a PRR form will be filled out and logged (section (b) (4) after segregation of nonconforming product. In addition, section (b) (4) indicates that the "form shall be filled out no later than three working days after the unit(s) is/are rejected".

For sterilization failures specifically; written procedure no. (b) (4) titled "Corrective and Preventive Action System" (Exhibit #67), designates on section (b) (4), table (b) (4) magnitude for (b) (4). The same table indicates that for these instances to (b) (4) which is the Non-Conformance Analysis and Report procedure. Mr. Berly indicated that for sterilization failures the procedure requires to initiate a nonconformance (NCR) investigation, thus escalating the investigation directly to a level higher than a PRR.

Given this, for the job rejected on 11/28/06, an NCR was logged on 1/10/07, approximately (b) (4). Written procedure no. (b) (4) titled Non-Conformance Analysis and Report (Exhibit #65), does not provide for timeframes to log, open and/or initiate an investigation (NCR) for sterilization failures after any given defect is noticed and reported as a non-conformance or PRR.

Mr. Berly and Mr. Murillo indicated that for this specific incident, (b) (4) was generated (Exhibit #45) and a NCR was indeed logged into the "Non-conformance Report Index" on (b) (4) with number (b) (4) (Exhibit #64). Mr. Murillo indicated that the NCR was voided on (b) (4) (Exhibit #68) as the issue would be covered, investigated, and documented as part of NCR number (b) (4) which was logged on 9/26/06 and initially reported on 10/16/06 (Exhibit #43).

I indicated to them that as per procedures, any sterilization failure will require a higher level investigation or NCR. I also indicated that at the moment of the incident there was no assurance that the issue was similar to the one covered by (b) (4). I added that approximately (b) (4) after the incident an NCR was logged and initiated, and that this is a very long period of time compared to the three day timeframe for PRR's which are, besides an initial containment action, a less stringent investigational tool. I also reiterated that written procedure, no. (b) (4) titled Non-Conformance Analysis and Report

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(Exhibit #65), does not provide for timeframes to log, open and/or initiate an investigation (NCR) for sterilization failures after any given defect is noticed and reported as a non-conformance or PRR.

(b) (6) Mr. Berly, and Mr. Ganion acknowledge the observation. Mr. Berly indicated that the Non-Conformance procedure has been updated and improved since some time ago. He added that the current version will be updated to be clearer and to reflect changes based on the inspectional observations. Mr. Ganion agreed and added that any detail or concern expressed during the inspection will be considered for further improvements in any pertinent area or procedure.

On 12/14/07, during the inspection closeout, Mr. Berly provided a copy of a draft version for the updated Non-Conformance Analysis and Report written procedure (Exhibit #63) and added that more changes will be added. I indicated that the corrections taken will be verified during the next inspection.

## REFUSALS

No refusals were encountered during this inspection.

## GENERAL DISCUSSION WITH MANAGEMENT

On 12/14/07, I held a closing meeting with Medtronic Puerto Rico Operations, Co. officials in which I explained all the activities performed during my inspection. Present during the meeting were Mr. Gerardo Mari-Roca, Plant Manager, Mrs. Betsy Rosario, Sr. QA/QS Manager, Mr. Rafael Berly-Torres, Regulatory Compliance Manager, Mr. Miguel O. Beltrán-Delgado, Sr. QA/QS Manager for MPROC Juncos, Mr. Norman Ganion, Sr. Principal Auditor (Minneapolis, MN) plus several other managers and section heads. Please refer to Exhibit #69, for the attendance sheet of the closing meeting. Two verbal observations were indicated and discussed. Mr. Mari-Roca and Mr. Ganion expressed their commitment to voluntarily correct the observations immediately. Mr. Berly provided a draft copy of the new version of the NCR written procedure which will address part of the observations. I took this opportunity to address on the importance of good communication and documentation practices between businesses units in the work place, for example, CDRM and Neuromodulation. I also stressed on the importance of implementing corrective actions which may apply to other similar situations. Please refer to the "Objectionable Conditions and Management Response" section of this report for details.

I reminded Mr. Mari-Roca that even though the current inspection disclosed only two verbal observations, his firm is still responsible to comply with all the regulations pertinent to their

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operations as the current inspection was not an all-inclusive inspection and it only covered part of the whole quality system. I also indicated that legal sanctions including seizure, injunction, civil money penalties and prosecution are available to FDA if establishments do not voluntarily correct serious conditions. No other issues were discussed and I closed the inspection.

#### **SAMPLES COLLECTED**

No samples were collected during this inspection.



LTJG Hector J Colon Torres, Investigator  
SJN-DO, Ponce RP



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### Adverse Event Report

**MEDTRONIC PUERTO RICO, INC. SPRINT FIDELIS IMPLANTABLE TACHY LEAD**

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**Model Number** 6949

**Device Problems** Capture, failure to; Impedance, high; Lead(s), fracture of; Oversensing

**Event Date** 10/30/2004

**Event Type** Injury **Patient Outcome** Other;

**Event Description**

Apparent lead fracture, no capture, high impedance, and intermittent oversensing.

**Manufacturer Narrative**

Attempts were made to obtain additional information from the user facility regarding this event. The information submitted reflects all relevant data received. Notification that this event does not meet the user facility's reporting criteria will be filed internally if it is received after this report is submitted. - evaluation summary - lfj014535v proximal conductor fractured; full lead returned.

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**Brand Name** SPRINT FIDELIS  
**Type of Device** IMPLANTABLE TACHY LEAD  
**Baseline Brand Name** SPRINT FIDELIS  
**Baseline Generic Name** IMPLANTABLE TACHY LEAD  
**Baseline Catalogue Number** NA  
**Baseline Model Number** 6949  
**Baseline Device Family** IMPLANTABLE TACHY LEAD  
**Baseline Device 510(K) Number**  
**Baseline Device PMA Number** P920015  
**Baseline Shelf Life Information** Yes  
**Baseline Preamendment?** No



**Transitional?** No  
**510(K) Exempt?** No  
**Shelf Life(Months)** 24  
**Date First Marketed** 09/02/2004  
**Manufacturer (Section F)** MEDTRONIC PUERTO RICO, INC.  
 Road 149  
 Km 56.3, Box 6001  
 Villalba PR \*  
 S  
**Manufacturer (Section D)** MEDTRONIC PUERTO RICO, INC.  
 Road 149  
 Km 56.3, Box 6001  
 Villalba PR \*  
 S  
**Manufacturer (Section G)** MEDTRONIC PUERTO RICO OPERATIONS CO.,  
 VILLALBA  
 Rd. 149, Km. 56.3  
 Call Box 6001  
 Villalba PR 00766  
**Manufacturer Contact** Sandra Dole  
 7000 Central Avenue N.E.  
 Minneapolis , MN 55432  
 (763) 514 -4059  
**Device Event Key** 622539  
**MDR Report Key** 632971  
**Event Key** 601785  
**Report Number** 2649622-2005-00086  
**Device Sequence Number** 1  
**Product Code** LWS  
**Report Source** Manufacturer  
**Source Type** Health Professional  
**Reporter Occupation** Invalid Data  
**Remedial Action** Other  
**Type of Report** Initial  
**1 Device Was Involved in the Event**  
**1 Patient Was Involved in the Event**  
**Date FDA Received** 01/10/2005  
**Is This An Adverse Event Report?** No

**Device Operator** Lay User/Patient  
**Device MODEL Number** 6949  
**Was Device Available For Evaluation?** Device Returned To Manufacturer  
**Is The Reporter A Health Professional?** No Answer Provided  
**Was the Report Sent to FDA?** No  
**Distributor Facility Aware Date** 10/30/2004  
**Device Age** 1 mo  
**Event Location** Hospital  
**Was The Report Sent To Manufacturer?** No  
**Date Manufacturer Received** 10/30/2004  
**Was Device Evaluated By Manufacturer?** Yes  
**Date Device Manufactured** 10/04/2004  
**Is The Device Single Use?** Yes  
**Is the Device an Implant?** Yes  
**Is this an Explanted Device?**  
**Type of Device Usage** Initial  
**Removal/Correction Number** NI

Database last updated on January 06, 2009

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Center for Devices and Radiological Health / CDRH



36553 HFI-35

OCT 1 2007

Food and Drug Administration  
Center for Devices and  
Radiological Health  
9200 Corporate Blvd  
Rockville, MD 20850

**WARNING LETTER**

Peter Wehrly  
Senior Vice President and President, Spinal and Biologics  
Medtronic Incorporated  
1800 Pyramid Place  
Memphis, Tennessee 38132

Re: SATELLITE™ Spinal System and ARCUATE™ Vertebral Augmentation System

Dear Mr. Wehrly:

The Office of Compliance (OC) in the Center for Devices and Radiological Health (CDRH) has reviewed various portions of the Surgical Technique Manual for the SATELLITE™ Spinal System, which was provided by Medtronic Sofamor Danek, Memphis, TN to the OC via email on Friday, July 20, 2007. The SATELLITE™ Spinal System is a device within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), because it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. The device was cleared for marketing under premarket notification (510(k)) submission numbers K051320 (cobalt chrome spheres) and K060415 (PEEK Optima LTI spheres). As discussed below, the manual reveals that the device is being distributed for intended uses and indications that represent major changes or modifications in the intended use and design of the device requiring submission of either a new premarket notification submission (510(k)), or an application for premarket approval (PMA) (21 C.F.R. 807.81 (a)(3)(i) & (ii)).

The cleared SATELLITE™ Spinal System consists of spheres manufactured from either cobalt chrome or PEEK OPTIMA LTI, which are available in sizes between 9.5 mm and 19 mm. The letters clearing the device for marketing include the following Indications for Use Statement:

The SATELLITE™ Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal.

The SATELLITE™ Spinal System is intended to be used with bone graft.



The clearance letters state, in accordance with Section 513(i)(1)(E) of the Act, that the following limitation must be prominently displayed, in close proximity to the trade name, in all labeling for the device, including pouch, box and carton labels, instructions for use, and other promotional materials:

The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.

The intended uses for the SATELLITE™ Spinal System described in the Surgical Technique Manual provided by your firm represent major changes or modifications to the cleared intended uses for this device that could significantly affect its safety or effectiveness. Specifically:

- Step 1 in the Manual states that "The patient is placed on the operating table in the prone position," indicating that a posterior approach is intended. However, Step 1 in Exhibit 14 of K051320 states: "The patient is placed on the operating table in a supine position," indicating that an anterior approach is intended.
- The Surgical Technique Manual does not include a step for the implantation of bone graft, contrary to the cleared intended use of the device.
- The Surgical Technique Manual describes a non-fusion procedure, in that there is no specific mention of either bone graft insertion or bony fusion, contrary to the statement required to be displayed, as described above.
- The instruments described by the Surgical Technique Manual provided by your firm include an 8 mm Trial and an 8 mm Sphere Curette, suggesting implantation of an 8 mm sphere. The cleared device includes spheres between the 9.5 and 19 mm.

As described above, your device is adulterated under section 501(f)(1)(B) of the Act [21 U.S.C. 351(f)(1)(B)] because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act is deemed satisfied when a PMA is pending before the agency (21 U.S.C. 807.81(b)).

The kind of information you need to submit in order to obtain approval or clearance for your device is described on the internet at <http://www.fda.gov/cdrh/devadvise/3122.html>. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

The Office of Compliance requests that Medtronic Sofamor Danek immediately cease the dissemination of promotional materials for SATELLITE™ Spinal System which include the intended uses described above. Please submit a written response to this letter within fifteen (15) working days of receipt of this letter describing your intent to comply with this request, listing all promotional materials for SATELLITE™ Spinal System the same as or similar to those described above, and explaining your plan for discontinuing use of such materials.

The Office of Compliance acknowledges that, on July 30 and 31, 2007, Medtronic Sofamor Danek emailed the Office of Compliance to indicate that Medtronic Sofamor Danek would initiate a corrective and preventive action (CAPA) item to address the inappropriate distribution of the SATELLITE™ Spinal System Surgical Technique Manual, and provided additional labeling material for the device, including a draft package insert and a draft package label. On September 14, 2007, Medtronic Sofamor Danek emailed the Office of Compliance to indicate that the firm is in the process of initiating a recall of the SATELLITE™ Spinal System Surgical Technique Manual. The information provided, however, does not completely address the concerns described in this letter. To address the concerns described in this letter, a CAPA which includes, but is not limited to the following is needed:

1. The cause of nonconformities relating to the SATELLITE™ Spinal System's Surgical Technique Manual;
2. The actions needed to correct and prevent recurrence of the nonconformities relating to the SATELLITE™ Spinal System's Surgical Technique Manual (i.e., removing product from the market, notification that the information disseminated by the product is not cleared via 510(k), assessment of the potential hazard to health caused by the dissemination of the product, recall strategy); and
3. The corrective and preventive action to ensure that above actions are effective (verification or validation).

Please provide this information in your response to this letter.

For your information, the FDA has located a press release dated September 27, 2006, on your website [www.medtronic.com](http://www.medtronic.com), that announces the availability of the ARCUATE™ Vertebral Augmentation System in the United States. However, a review of our records indicates that your firm's 510(k), K063248, for the ARCUATE™ Vertebral Augmentation System was not cleared until March 13, 2007. In addition, the press release made the following claims, for which you have not obtained marketing clearance or approval:

- "...controlled cement delivery system;"

- "The proprietary ARC™ Osteotome creates arcs within the existing bone structure, allowing a preferential flow of cement into arcs and cancellous bone openings...may allow for a better distribution of cement across the vertebral body minimizing the number of incisions and steps necessary to create a biomechanically stable support for the spine;"
- "... may reduce procedure time and limit radiation exposure by taking the surgeons' hands out of the radiation field;" and
- "... may mean abbreviated procedure time, potentially shorter recovery times and the possibility of less pain."

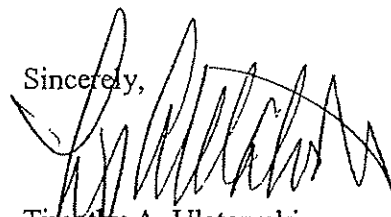
The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials comply with each applicable requirement of the Act and FDA implementing regulations.

Failure to correct the promotional violations discussed above may result in FDA regulatory action, including seizure, injunction, or civil money penalties without further notice.

Please direct your response to Mr. William MacFarland at the Food and Drug Administration, 2094 Gaither Road, HFZ-343, Rockville, Maryland 20850, facsimile at (240) 276-0129. We remind you that only written communications are considered official.

We request a meeting with your firm to discuss your strategy to bring your medical devices into compliance with the Act. Please contact Mr. MacFarland to arrange this meeting. Please be prepared to discuss your corrective action plan for compliance and your efforts to prevent the recurrence of these deficiencies.

Sincerely,



Timothy A. Ulatowski  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

Cc: Mr. William A. Hawkins, President and Chief Operating Officer  
Medtronic Incorporated 710 Medtronic Parkway Minneapolis, MN 55432-5604

Susan Alpert, Ph.D., M.D., Senior Vice President - Chief Quality and Regulatory  
Officer  
Medtronic Incorporated 710 Medtronic Parkway Minneapolis, MN 55432-5604



**Medtronic**

P920015 | R12 | C1

Medtronic, Inc.  
Cardiac Rhythm Management  
1015 Gramsle Road  
Shoreview, MN 55126-3082  
www.medtronic.com

763.505.7088  
763.505.7878

March 2, 2006

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, MD 20850

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**Re: P920015 - Twelfth Annual Report**

This report covers a one-year period from December 10, 2004 through December 9, 2005.

Enclosed, in compliance with 21 CFR 814.84, is the twelfth annual report for the following devices, approved under PMA P920015:

- Model 6963, 6966, and 6999 leads for the initial Transvene® lead system
- Model 6933, 6936, and 6939 leads for Transvene® DF-1 system
- Model 6937 Transvene® SVC lead
- Model 6707 lead adaptor
- Model 6932 Sprint™ lead
- Model 6942 Sprint™ lead
- Model 6943 and 6945 Sprint™ leads
- Model 6944 Sprint™ Quattro™ lead
- Model 6947 Sprint™ Quattro Secure™ lead
- Model 6996 SQ lead system and 6996T tunneling tool
- Model 6726 DF-1 Y-Adaptor/Extender Kit
- Model 6949 and 6931 Sprint Fidelis™ leads
- Model 6948 and 6930 Sprint Fidelis™ leads

The following information is included in this report:

- Summary of changes reportable under 21 CFR 814.39(a) and (b)
- Summary and Bibliography of Published and Unpublished Reports
- Device Experience Information

Two copies of this submission are provided. This submission contains confidential commercial and trade secret information and Medtronic requests it be given the maximum protection provided by law.



Please contact the undersigned to obtain additional information concerning this report.

Sincerely,

MEDTRONIC, INC.

*Michelle Nivala*

Michelle Nivala  
Regulatory Affairs Specialist  
Cardiac Rhythm Management  
Tel: 763.505.7863  
Fax: 763.505.7877  
E-mail: michelle.d.nivala@medtronic.com



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# SUMMARY OF CHANGES MADE

## Changes Pursuant to 21 CFR 814.39(a) - PMA Supplements to PMA P920015

### Supplement 31

**Description/Models:** This supplement requested approval for a change to the monolithic controlled-released device (MCRD) and addition of dexamethasone sodium phosphste (DSP) to the Models 6945, 6943 and 6947 Leads.

**Filed:** September 10, 2004

**Status:** Approved February 7, 2006

This supplement requested approval for material and steroid changes to the monolithic controlled release device (MCRD) used in selected models of Medtronic pacing leads. The binder material changed from polyurethane to silicone and the steroid changed from dexamethasone sodium phosphate (DSP) to dexamethasone acetate (DXAC).

### Supplement 32

**Description/Models:** This supplement requested approval for a change in aeration time following sterilization of Models 6930/6931 and 6948/6949 Leads.

**Filed:** September 2, 2005

**Status:** Approved December 1, 2005

A 30-Day Notice PMA Supplement was submitted for approval to optimize the aeration process used to remove steriliant residuals for the lead models listed above, following ethylene oxide sterilization performed at the Medtronic (b)(4) (b)(4)

### Supplement 33

**Status:** Withdrawn

PMA Supplement P920015/S033 filed December 7, 2005 was withdrawn on December 19, 2005. The changes referenced as part of the

P890003/S093 bundled submission did not apply to PMA P920015, as it was erroneously referenced.

#### **Supplement 34**

**Status:** Withdrawn

PMA Supplement P920015/S034 filed December 6, 2005 was withdrawn on December 19, 2005. The changes referenced as part of the P890003/S097 bundled submission did not apply to PMA P920015, as it was erroneously referenced.

## Changes Made Pursuant to 21 CFR 814.39(b)

### CHANGE 1: Improve Process for Crimping

#### Process Change

Revised crimping operation from a manual four indent crimper to a manual eight indent crimper.

#### Description of Modification

To optimize the contact area between the connector pin and connector pin cap, the crimp was changed from four to eight indents to allow an increase in the contact area. Leads now are built with a manual eight indent crimper.

*Models Affected:* 6943, 6945, 6947, 6949, 6948, 6930 and 6931.

#### Reasons for Change

This change was implemented to reduce the potential of intermittent continuity between the pin cap and the pin of the lead. Increasing the number of indents at the crimp from four to eight, allows an increase in contact area.

The new crimp was validated and documented. (Reports 05VR.016 and 05VR.049). Three lots of thirty (30) were used for the validation of this process to demonstrate a confidence level of 95% with 95% reliability. The process met a Cpk of greater than 1.33 meeting pre-determined acceptance criteria.

#### Rationale

This change was determined to be Annual Reportable because the change:

- Does not affect the performance or design specifications, circuits, components, ingredients, principal of operation or physical layout of the devices.
- Does not affect the contraindications, warning and precautions or other information contained in the product labeling.
- Does not affect the indications for use of the devices.
- Does not affect safety or effectiveness of the devices and is considered a minor manufacturing change.



Medtronic, Inc.  
Cardiac Rhythm Disease Management  
8200 Coral Sea Street NE  
Mounds View, MN 55112  
www.medtronic.com

Phone 763.526.0000  
Fax 651.367.0603

December 7, 2007

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

**Subject: Annual Report for P920015**

To Whom It May Concern:

Enclosed, in compliance with 21 CFR 814.84, is the Annual Report for the above referenced PMA number. This report is submitted in compliance with the conditions of approval associated with this PMA.

This Annual Report covers the time period from December 31, 2007 to September 30, 2007.

**Table 1** identifies the device model numbers and brand names for the products included in this Annual Report.

**Table 1: Products under P920015**

Model Numbers	Brand Names
6963, 6966, 6999	Leads for initial Transvene® Leads System
7217B <sup>1</sup>	Pacer-Cardioverter Defibrillator
6933, 6936, 6939	Leads for Transvene® DF-I System
6934	Lead for Transvene® Right Ventricular System
6934S <sup>2</sup>	Lead for Transvene® Right Ventricular System
6937	Transvene® SVC Lead
6932, 6942, 6943, 6945	Sprint™ Leads
6944	Sprint™ Quattro™ Lead
6947	Sprint™ Quattro Secure™ Lead
6996 SQ	Subcutaneous Lead System
6948, 6949, 6930, 6931	Sprint Fidelis Leads
<b>Accessories</b>	
6707	Lead Adaptor
6996T	Tunneling Tool
6725	Pin-Plug Kit
6726	DF-I Y-Adaptor/Extender Kit

<sup>1</sup>P900061 is the master PMA file for this model; therefore, this model will be reported under P900061 only.

<sup>2</sup>P980050 is the master PMA file for this model, therefore, this model will be reported under P980050 only.



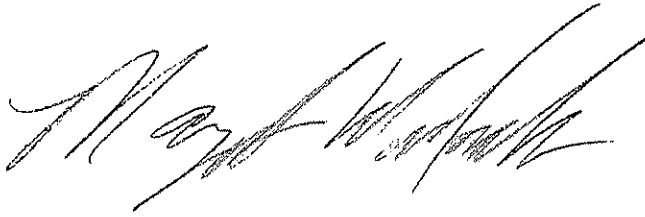
*Alleviating Pain · Restoring Health · Extending Life*

This submission contains confidential commercial or trade secret information and Medtronic requests that it be given maximum protection provided by the law.

Three (3) copies of this Annual Report are being submitted (two (2) paper copies and one (1) CD-ROM). Per FDA instructions, an eCopy is being provided and the CD-ROM is an exact copy of the paper copies.

If you have any questions, please contact me at the telephone number or email address listed below.

Sincerely;  
**MEDTRONIC, INC.**



Margaret M. DePuydt, P.E., RAC  
Senior Regulatory Affairs Specialist  
Cardiac Rhythm Disease Management  
8200 Coral Sea Street N.E.  
Mounds View, MN 55112  
Tel: (763) 526-2382  
Fax: (651) 367-0603  
Email: [margaret.m.depuydt@medtronic.com](mailto:margaret.m.depuydt@medtronic.com)

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**Reporting period December 31, 2006 to September 30, 2007**

# CONDITIONS OF APPROVAL

## Required PMA Conditions of Approval – Requirement 1

Beyond the standard “Conditions of Approval for Implantable Defibrillators and Programmers,” there is no additional information required in the form of post-approval report. Included in this Annual Report are:

- See Attachment A– Device Experience
- See Attachment B – Product Performance Report

# SUMMARY OF CHANGES

## Changes Reported Pursuant to 21 CFR 814.39(a):

The following PMA Supplements were submitted and/or approved during the reporting period:

Supplement Number	Submission Description	Date Submitted	Date Approved
S036	Addition of a paperless chart recorder to the sterilization operations	11/20/06	12/11/06
S037	Minor design and manufacturing changes to improve the DF-1 leg strength and handling characteristics of leads	5/14/07	7/3/07
S038	Minor manufacturing changes and a vendor change for the IS-1 connector sleeve mold	9/12/07	Pending Approval

## Changes Reported Pursuant to 21 CFR 814.39(b):

Minor modifications were made to Medtronic's devices during the reporting period and these modifications are described below. These minor modifications were not submitted as PMA supplements because they do not affect the safety or effectiveness of the device and do not impact the Conditions of Approval listed in the FDA approval letters. These changes are included within this annual report.

### 1. NEW PINS Due to Package Labeling Changes

#### Reason for Change

News Pins were created due to Packaging Labeling and Bill of Materials changes to lead products for the upcoming Final Package Automation (FPA) line, the general label text was updated.

#### Models Impacted

6944 and 6947

### Nature and Scope of Change

New PINs are being created for several lead models manufactured at MPROC-Villalba. These PINs will incorporate new package label formats /layouts and some labeling/literature component updates. The package labels being updated include the sterile package label, the shelf box label and the FYR (For Your Records) label.

The changes include:

- Update to the lead picture graphic; where a distal and proximal end of the lead may have been shown, the full lead body is now shown on the shelf box label.
- The lead graphic has been removed from the sterile package label.
- The lead length and model number have been removed from the text information: the lead length is now included as part of the lead graphic. The model number is already included in the product title.
- Update the label address to include Villalba, Puerto Rico as manufacturing site per standard CCRA-038 to read: "Manufactured in/at: Villalba, Puerto Rico, USA"
- Symbols for Storage, Serial Number, and Use By added.
- The barcode has been changed from HIBC to UCC format.
- The FYR (For Your Records) labels have been updated to a new format. Peel off labels were previously part of the sterile package label but are now an individual label.
- IS-1 connector type has been added to side label and separate sticker has been eliminated.
- Distal end fixation type graphic has been added to side label on models that didn't have it previously.
- Trade name may have been updated on some models not done previously to reflect corporate guidelines.

See the list below for existing and new label part numbers:

Model Number	Existing Label Part Number	New Label Part Number
6944	633510	A12009
6947	633615	A12049

In addition to the label text changes, the shelf box part number was changed to 350381-001 from 19434-001 to reflect the following labeling changes:

- There is a slight variation in the location of the barcode print on the bottom.

- The new box width and length are 1/8" smaller than the current measurement. The box height has not changed.
- The box color and raw materials, and construction methods are the same.

In addition to the shelf box label text changes, the following changes regarding processes and components used for each PIN will be changed as follows:

- The software for printing the labels and generating the text is changing from LabelVision to Formscape.
- The label stock was also redesigned. Previously all labels were printed on one sheet. Now the sterile package, shelf box, and FYR labels will each be printed on a different sheet.
- The Medtronic logo graphic has been removed from the shelf box seal labels.
- A Disclaimer of Warranty and general warning literature piece has also been added to the bill of materials for PINs that currently may not include it.
- A new literature envelope was also implemented, the design of the envelope opening was slightly modified to allow for use on the FPA line automated equipment and the text "Pacing Lead Information, Forms to be Completed" and the Medtronic logo were removed and do not appear on the new envelope.

### Testing

No product testing is required as the changes are minor formatting differences to created standardization in labeling of Therapy Delivery product and do not affect the use or indications for use of the products.

The new Formscape labeling software has been validated. The automated equipment used as part of the Final Package Automation line (FPA) will be validated as implemented.

### Rationale for Change

This change is annual reportable based on the following rationale:

- These changes are minor in nature, with a minor affect to the package labeling and do not affect indications for use.
- The change is not a technology or performance, manufacturing site, control mechanism, operating principle, energy type, environmental specification, performance specification, dimensional change, ergonomic or patient/use interface, software or firmware change.
- The change is being made for standardization purposes and are intended to be used when the packaging line becomes automated, which will be qualified before implementation.

- The change is not designed to improve safety based on clinical experience.
- Additional clinical data is not necessary to establish safety and effectiveness.
- The change is qualified to original specifications; FDA recognized test, standard, or guidance.
- There are no new safety and effectiveness issues raised as a result of the change.
- There are no new or increased risks associated with the change.
- The change does not affect or change device sterility, packaging, sterilization site, sterilization method or expiration date.
- The change is not due to a recall or field corrective action.
- This change does not affect safety and effectiveness of the products and therefore can be reported via Annual Report.

## 2. Subject: Post Cure Change

### Reason for Change

The change being implemented will result in yield improvement.

### Models Impacted

6726, 6930, 6931, 6932, 6940, 6942, 6943, 6944, 6947, 6948, 6949

### Nature and Scope of Change

A minor change for the post cure process was made to the F-1 connector insulation, which was changed as a strain relief (part number (b) (4) from (b) (4) (b) (4) was made. There were no other manufacturing or process changes implemented with this minor change. This change was made to improve manufacturing yield only and not as a result of a field or quality issue. All dimensional and mechanical requirements for the tubing remain unchanged. There are no specification changes, except for the post cure change.

### Testing

This minor change in the post cure process was previously made in other Medtronic leads models several years ago. At that time, a post-cure design of experiment (DOE) was completed at that time, along with crush testing. The tubing has performed within expectations during the life of the product and the same post-cure is currently employed on the multi-lumen tubing which is used on the leads of all

Sprint Quattro, and Sprint Fidelis. (part number (b) (4) A comparison is listed below:

Model Name	Part Number	Raw Material	Post Cure	Durometer
Sprint Fidelis	(b) (4)			
Sprint Quattro		(b)(4)		

The differences between the two tubes are that the (b) (4) is single-lumen and has much thicker walls based on the inherent design of the product. As such this minor change has no impact on the component performance. The two tubes have different durometers; however they are of the same chemical family. A comparison between the two components is listed below:

Part Number	Tensile Strength	Elongation	Toughness	Durometer	Extractables
(b) (4)					
			(b)(4)		

The single-lumen tubing is used in the connector portion of the lead, located in the device implantation pocket, whereas the multi-lumen tubing is subject to tortuous anatomy. The more difficult load conditions on the tubing and history of acceptable performance of the multi-lumen tubing indicate this change will have no impact on the function of the tubing.

Differential Scanning Calorimetry testing was also performed on the (b) (4) to determine the amount of cure in the old and proposed post-cure conditions. (b) (4) showed no significant difference in amount of cure between the two post-cure settings. Testing included ensuring that all mechanical and design specifications were met. There were no anomalies noted during testing.

Additionally, there were no new or increased risks and no impact on existing device biocompatibility assessments.

### Rationale for not filing a PMA-S

- The change does not affect labeling or indications for use.
- The change is not a technology or performance, manufacturing site, control mechanism, operating principle, energy type, environmental specification, performance specification, dimensional change, ergonomic or patient/use interface, software or firmware change.
- The change is a manufacturing change for a component that allows modification to the post-cure time and temperature as previously outlined. The change aligns the post-cure requirements with existing process requirements of the multi-lumen tubing that is held to more stringent requirements. Therefore, the process change was modified based on

experience with that tubing part number and confirmed by additional testing on the single-lumen tubing. As previously outlined, testing demonstrated that the component meets requirements.

- The change is not designed to improve safety based on clinical experience.
- Additional clinical data are not necessary to establish safety and effectiveness.
- There are not any new safety and effectiveness issues raised as a result of the change.
- There are not any new or increased risks associated with the change.
- The change does not affect or change device sterility, packaging, sterilization site, sterilization method or expiration date.
- This change is not due to a recall, field performance issues, or field corrective action.

### 3. Addition of Weight Balance to Process (b) (4) (b)(4)

#### Reason for Change

The change is being made to clarify the process and avoid non-conformances.

#### Models Impacted

6930, 6931, 6932, 6942, 6943, 6944, 6945, 6947, 6948

Note: This change was previously submitted in P980016/R009, dated September 28, 2007 and is currently under review by FDA.

#### Nature and Scope of Change

Process (b) (4) Revised manufacturing operation to include instructions about w----- n needs to be checked, related to the aeration time. Operator pulled the baskets from the machine prior to the aeration time limit.

Process (b) (4) Revised manufacturing operation to include the instructions about w----- n needs to be checked related to the aeration time. The weight balance that has been added to the process has the capability of printing a bar code which includes the weight information. The SADR system has the capability of reading the bar code; therefore the operator will now weigh the canister and will print the bar code, which will be read by the SADR system, so the information no longer will be put manually into the SADR system. This did not affect any product in the field.

#### Testing

An installation/operational qualification testing was performed for the SADR system to establish confidence that the equipment and its support systems are

installed per manufacturer specifications and Medtronic requirements. All testing passed and no anomalies were identified.

### Rationale for not filing a PMA-S

- The change does not affect the labeling or indicates for use.
- The change is not a technology or performance, manufacturing site, control mechanism, operating principle, energy type, environmental specification, performance specification, dimensional change, ergonomic or patient/use interface, software or firmware change.
- The change is not a manufacturing change and it is not a change in the QA inspection procedure for a component or finished device.
- The change is not designed to improve safety based on clinical experience.
- Additional clinical data are not necessary to establish safety and effectiveness.
- The change is qualified to original specifications; FDA recognized test, standard, or guidance.
- There are not any new safety and effectiveness issues raised as a result of the change.
- There are not any new or increased risks associated with the change.
- The change does not affect or change device sterility, packaging, sterilization site, sterilization method or expiration date.
- This change is not due to a recall, field performance issues, or field corrective action.

## 4. Apply Primer To The Outer Coil Weld Assembly

### Reason for Change

The change being implemented will result in yield improvement.

### Models Impacted

6930, 6931, 6948, 6949

### Nature and Scope of Change

As part of the outer coil weld assembly, used for the IS-1 legs of Fidelis Models 6949, 6948, 6931, and 6930 a piece of (b)(4) to a

(b)(4) The (b)(4) and is (b)(4)  
(b)(4) ab (b)(4) for su

----- teps. The bond does not serve any functional purpose in the finished device.

A good (b)(4) is not always formed between the (b)(4) as they sometimes separate when handled, requiring (b)(4) scrapped. As a (b)(4) characterized (b)(4) has been applied to the (b)(4) prior to (b)(4) to increase the (b)(4)

1. This (b)(4) is not a new material (b)(4) operating (b)(4) is currently used to (b)(4) overlay.

There were no other manufacturing or process changes associated with this minor change. This change was made to improve manufacturing yield only and not as a result of a field or quality issue. All dimensional and mechanical requirements for the (b)(4) remain unchanged. There are no specification changes, except for the (b)(4) change.

### Testing

The (b)(4) has demonstrated its ability to improve the (b)(4) between (b)(4) and (b)(4) in other parts of the lead, and can therefore (b)(4) these materials in the (b)(4) for Fidelis leads. Additionally, this (b)(4) is not a new material (b)(4) used in a similar fashion for other (b)(4) ns. For these reasons, this change will be implemented without (b)(4) ng reliability testing. There is no change to the form, fit, or function of the final product.

(b)(4) prior to (b)(4) it to (b)(4) is a widely used (b)(4) process. (b)(4) nge w (b)(4) y special processes and due to the nature of the change and location of the (b)(4) testing is required to implement this change.

### Rationale for not filing a PMA-S

- No change in materials as this adhesive is used for priming other areas of lead.
- No biological assessment (b)(4) y contained in the product biological assessment as (b)(4) (b)(4) No change in device form, fit or function. Change i (b)(4) yield.
- The change does not affect the labeling or indicates for use.
- The change is not a technology or performance, manufacturing site, control mechanism, operating principle, energy type, environmental specification, performance specification, dimensional change, ergonomic or patient/use interface, software or firmware change.
- The change is not a manufacturing change and it is not a change in the QA inspection procedure for a component or finished device.
- The change is not designed to improve safety based on clinical experience.

- Additional clinical data are not necessary to establish safety and effectiveness.
- The change is qualified to original specifications; FDA recognized test, standard, or guidance.
- There are not any new safety and effectiveness issues raised as a result of the change.
- There are not any new or increased risks associated with the change.
- The change does not affect or change device sterility, packaging, sterilization site, sterilization method or expiration date.
- This change is not due to a recall, field performance issues, or field corrective action.

P920015/R13

### PMA Annual Report Review

PMA Number: P920015/R013

Company Name: Medtronic, Inc.

ODE Reviewer: Vivianne Holt *V. Holt 4/26/07* OC Reviewer: n/a

ODE Branch: FDA/CDRH/ODE/DCD/PDLB OC Branch: n/a

#### Basic Information

This annual report covers the reporting period from December 10, 2005 to December 31, 2006.

The following device models are covered in this report:

- Model 6963, 6966, and 6999 leads for the initial Transvene® lead system**
- Model 6933, 6936, and 6939 leads for Transvene DF-1 system Model 6934 leads for Transvene® Right Ventricular system**
- Model 6937 Transvene® SVC lead**
- Model 6707 Lead adaptor**
- Model 6932, 6942, 6943 and 6945 Sprint™ leads**
- Model 6944 Sprint™ Quattro™ lead**
- Model 6947 Sprint™ Quattro Secure™ lead**
- Model 6996 SQ lead system and 6996T tunneling tool**
- Model 6725 Pin-Plug Kit**
- Model 6726 DF-1 Y-Adaptor/Extender Kit**
- Model 6948, 6949, 6930, and 6931 Sprint Fidelis™ leads**

**Note:** The Model 6948, 6949, 6930, and 6931 Sprint Fidelis™ leads are the subject of a “Dear Doctor” letter dated March 21, 2007 (attached). These leads are indicated for single, long-term use in the ventricle. The leads have application for patients for whom implantable cardioverter defibrillators are indicated (6949 & 6931) or for whom arrhythmia management systems are indicated (6948 and 6930). The sponsor issued the “Dear Doctor” Letter because they had recently received reports from a limited number of implanting physicians indicating they had experienced higher than expected conductor fracture rates with Sprint Fidelis leads. In addition, FDA’s office of compliance (OC), acting on physician-submitted information regarding Sprint Fidelis fractures that occurred between September 2004 and February 2007, requested additional information in a letter dated March 7, 2007 (attached). The sponsor’s responses to OC’s letter have been received by FDA but OC has not yet notified ODE of their final decision. I reviewed the responses as part of the annual report review.

At this point, the sponsor claims their investigation suggests that variables within the implant procedure may contribute significantly to Sprint Fidelis lead fractures. In the Dear Dr. Letter, they notified physicians to take precautions to avoid severe bending or kinking of the distal end of the lead over the lead body while passing through tortuous vasculature. They also suggested that physicians should avoid excessive bending or kinking of the lead during lead suturing or pocket formation or both, to address fractures that occur around the suture sleeve. It is of note



that while the Dear Dr. Letter lists distal fractures and fractures around the suture sleeve, the response to OC's questions also lists DF-1 cable fractures within the RV or SVC connector legs as a location where fracture has occurred. Also, in the response to OC, distal fractures are further broken down into DF-1 cable fracture proximal of the proximal RV coil/crossgroove and sense cable fractures in or near the cast zone.

The sponsor has not notified FDA of any current or proposed changes to the device design or manufacturing processes for the distal end or suture sleeve fractures. However, as of April 25, 2007 they had submitted a real-time review request for proposed changes to the strain relief in the DF-1 connector leg, DF-1 cables in the trifurcation and connector leg, and jumper tubing in the trifurcation. These changes address the observed DF-1 cable fractures within the RV or SVC connector legs although the sponsor has not explicitly stated that the changes were made in response to field failures.

The sponsor notes that performance of the model 6949 Sprint Fidelis lead currently followed in the System Longevity Study indicates lead survival of 98.9% at two years. Returned product analysis shows 6949 performance at 99.86% chronic fracture-free survival at two years. They provided comparison charts to other currently marketed leads:

**System Longevity Study**

<b>Lead Model</b>	<b>Survival at Two Years</b>
Sprint (6945)	99.1%
Sprint Quattro (6947)	99.3%
Sprint Fidelis (6949)*	98.9%

**Returned Product Analysis**

<b>Lead Model</b>	<b>Survival at Two Years</b>
Sprint (6945)	99.92%
Sprint Quattro (6947)	99.94%
Sprint Fidelis (6949)*	99.86%

\*This is the only Sprint Fidelis model for which there is sufficient reporting information due to the small implant population for the model 6948, 6931, and 6930 leads

Based on the data provided, the Sprint Fidelis lead survival rates appear to be within the normal limits for leads at two years. Therefore, no additional information will be requested at this time. See "Analysis of Explants, Deaths, and Returned Units," below, for additional information regarding the performance of the Sprint Fidelis leads.

**Attachments**

- Medtronic response to FDA/OC's letter of March 7, 2007 Reference MDR Reports for Sprint Fidelis Leads (includes "Dear Doctor" Letter)
- email from OSB dated February 7, 2007

**Reportable Changes**

Are any of the reportable changes intended to address issues observed in the field?

No  Yes

If yes, please list (by number) which changes are intended to address field issues and attach a brief description of those field issues: n/a

If no, has the sponsor provided a statement that none of the reportable changes are intended to address issues observed in the field?

No  Yes

The sponsor did not provide this statement; however, the nature of the changes (see descriptions below) makes it clear that they were not intended to address issues observed in the field.

Has the sponsor provided a detailed description of those field issues and documentation of when and how FDA was first notified of those field issues?  No  Yes n/a

**By checking “Annual Reportable” (AR) in the following table, I am asserting that the modification does not raise issues of safety or effectiveness.**

**ODE**

**OC**

(Choose Whether Design or Manufacturing Change)

Manufacturing/Design Change (by number or page number)	Device/Design Changes	Manufacture/Process Changes	Does OC Concur? (Please provide comment if not)
1. Editorial changes to work instructions to notify personnel to minimize heptane exposure to hands.	<input type="checkbox"/> AR <input type="checkbox"/> PMA-S <input type="checkbox"/> A/I <input type="checkbox"/>	<input checked="" type="checkbox"/> AR <input checked="" type="checkbox"/> 30-Day <input type="checkbox"/> A/I <input type="checkbox"/>	Concur <input type="checkbox"/> Not concur <input type="checkbox"/> Note: _____
2. Replaced labeling and traceability software to be consistent and current with the same validated software systems used in other Medtronic manufacturing facilities	<input type="checkbox"/> AR <input type="checkbox"/> PMA-S <input type="checkbox"/> A/I <input type="checkbox"/>	<input checked="" type="checkbox"/> AR <input checked="" type="checkbox"/> 30-Day <input type="checkbox"/> A/I <input type="checkbox"/>	Concur <input checked="" type="checkbox"/> Not concur <input type="checkbox"/> Note: <i>per email from Albert Moyal 5/3/07</i>
3. Editorial changes to work instructions to explicitly call out 100%	<input type="checkbox"/> AR <input type="checkbox"/> PMA-S <input type="checkbox"/> A/I <input type="checkbox"/>	<input checked="" type="checkbox"/> AR <input type="checkbox"/> 30-Day <input type="checkbox"/> A/I <input type="checkbox"/>	Concur <input type="checkbox"/> Not concur <input type="checkbox"/> Note: _____

inspection of stylets for bending after DSP solution is applied to the lead.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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**Note:** The changes listed above were not sent for OC review since changes 1 and 3 are editorial in nature and change 2 was a change to software programs that are already used and validated in other Medtronic facilities. Technically, these are manufacturing changes but they are not changes in which any of the manufacturing processes would be affected, hence these are annual-reportable changes. *Note: Change #2 also can firm w/ OC (5/3/07)*

**Analysis of Explants, Deaths, and Returned Units**

- An analysis of explants, deaths, and returned units has been provided and is adequate
- An analysis of explants, deaths, and returned units has not been provided, or is inadequate, or raises concerns (provide comment):

The report contained a summary of system experience for each model of device included in this report per the conditions of approval. The summary did not identify any patient deaths associated with the devices subject to this reports. The analyses of returned explants had failures of various types but no numerous or repeated mode failures through the family of leads. The sponsor provided health device alerts in the submission. The number of adverse events was few compared with the number of marketed leads. Based on an email from OSB dated February 7, 2007 (attached), Soma Kalb pulled the MDR's from the MAUDE database for ODE review. OSB noted that there are no deaths reported in Maude for the Sprint Fidelis model 6949 (this is the only Sprint Fidelis model for which there is sufficient reporting information due to the small implant population for the model 6948, 6931, and 6930 leads). They noted that there were 165 of 525 events in MAUDE with model 6949 reporting fractures or breakages. Some were distal fractures and some were proximal fractures. Some may have been related to the implant procedure and some to the explant procedure. Suture sleeve fractures can be related to sutures being tied too tight and fracturing the lead. There was at least one report that mentioned a proximal weld defect.

**Safety Alerts**

- A summary of safety alerts has been provided and is adequate
- A summary of safety alerts has not been provided, or is inadequate, or raises concerns (provide comment):

\_\_\_\_\_

\_\_\_\_\_

**Bibliography**

- A Bibliography has been provided and is adequate

A Bibliography has not been provided, or is inadequate (provide comment):

\_\_\_\_\_  
\_\_\_\_\_

### Recommendation

Complete final report, no response necessary. (Report OK Letter, APPB in CTS)

Incomplete final report, request additional information, 30-Day Notice, or PMA-S.  
(Deficiency Letter, RPT1 in CTS)

### Explanation of Decision

(Explain ODE “PMA-S”, “30-Day” or “A/I” Decisions from chart above)

**Additional Information Required:**

N/A

**Explanation of why 30-Day Notice(s) Required:**

N/A

**Explanation of why PMA Supplement(s) Required:**

N/A

Cancer -  
M. J. [Signature] 4/30/07



**Medtronic**

April 6, 2007

Medtronic, Inc.  
Cardiac Rhythm Disease Management  
1015 Gramsie Road  
Shoreview, MN 55126-3082  
www.medtronic.com

Phone 763.514.4000 763.505.7888  
Fax 763.505.7878 763.505.7877

FDA/CDRH Medical Device Reporting  
P.O. Box 3002  
Rockville, MD 20847-3002

Attention: Diane Dwyer

Reference: Letter of March 7, 2007, Reference MDR Reports for Sprint Fidelis Leads

The letter referenced above requested additional information regarding various Sprint Fidelis leads. Our response to each of your questions follows.

**Question:**

1. To assist us in determining the overall failure rate for the Sprint Fidelis defibrillator lead since first marketed in the U. S., please provide an Actuarial Survival Probability table for each Sprint Fidelis model your firm has marketed (models 6930, 6931, 6948, and 6949).

**Medtronic Response:**

1. In our discussion on March 19, 2007 you requested actual product performance data based on confirmed failures, rather than Survival Probability information. The following table details US Fidelis Lead actual product performance data through 01/31/2007, based on return product analysis.

Implant damage is defined as damage to the lead that occurs in the process of implanting the lead during the surgical procedure. Examples of implant damage are stylet perforation, cut or tear of insulation, dented or distorted conductors, and conductor fractures due to mishandling.

Electrical malfunction is defined as a hardware malfunction resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. Examples of breaks in the insulation include cuts, tears, depressions, environmental stress cracking (ESC) and metal ion oxidation (MIO). Examples of breaks in conductors include fractured conductors and incomplete crimps.

Non-electrical out of specification are other malfunctions or observations that do not affect electrical performance of the lead. Examples of non-electrical out of specifications include discoloration and indentations.

<i>Model</i>	<i>Initial Implants</i>	<i>Estimated Active Implants</i>	<i>Analyzed</i>	<i>Implant Damage</i>	<i>Electrical Malfunction</i>	<i>Non-Electrical Out of Specification</i>
6930	236	215	1	-	-	-
6931	5,387	4,917	99	12	22	-
6948	7,510	6,874	83	5	3	2
6949	144,311	129,047	1,631	350	213	33

**Question:**

**2. For each model number, please submit the number of Sprint Fidelis defibrillation leads manufactured, distributed, implanted and explanted in the U.S.**

**Medtronic Response:**

2. Please reference the following table for the number of Sprint Fidelis leads manufactured, distributed, implanted and explanted in the U.S.

Fidelis Model Number	Product Manufactured in US for Worldwide Use (as of 3/12/07)	US Sold (as of 3/12/07)	US Registered Implants (as of 3/12/07)	US Registered Explants (as of 3/12/07)
6930	3,690	274	253	3
6931	22,807	6,245	5,841	151
6948	27,107	8,626	7,883	140
6949	215,674	161,399	150,933	2,963

Note: Registered explants include leads that are replaced, removed, returned, capped, or non-functional. Returned leads include fully intact leads or lead segments.

**Question:**

**3. Submit any device failures confirmed by manufacturer failure analyses that have not been provided to FDA under the MDR reporting regulation (see Attachment 2).**

**Medtronic Response:**

3. In our discussion on March 19, 2007, you requested a table detailing the status of analysis, actual analysis results (if applicable), and other supporting detail for those leads referenced in Attachment 2 of your letter. As detailed in the attachment, all available analysis results have been submitted, or are scheduled for submission to the FDA. Please refer to Attachment 1 of this response for detail on each serial number referenced.

**Question:**

**4. Please describe any internal and/or regulatory action(s) taken in response to MDRs (internal actions such as manufacturing, labeling, training, design and/or quality assurance, and regulatory actions such as PMA supplement, 30 day notice, CAPA and recalls):**

- a) In reference to Attachment 1 (see items c, e through o, and q through t), there are reports for a total of 197 Sprint Fidelis model 6949 defibrillator leads prematurely explanted and confirmed with a fracture. One MDR for model 6949 (b)(4) (b)(4) involves a death during the implant procedure, with the MDR "manufacturer evaluation result code" reported as number (b)(4) (b)(4) device performed according to specifications) and the lead analysis revealed "distal conductor and coil was distorted and fractured in a manner consistent with overstress (implant damage)". For all confirmed lead fractures, breakages and

distortions, please describe any action(s) taken to address the occurrence of confirmed fractures observed with the device model 6949.

b) For manufacturer confirmed lead fractures associated with the Sprint Fidelis ICD lead models 6930, 6931, and 6948.

c) One model 6949 lead was mislabeled (See Attachment 1, item a: (b) (4) (b)(4))

Medtronic Response:

4a) Based on product field returns, Medtronic has identified four locations on the Fidelis Leads where conductor fractures have occurred. These locations are as follows: DF-1 cable fractures within the RV or SVC connector legs, DF-1 cable fractures proximal of proximal RV coil/crossgroove, sense cable fractures in/near the cast zone, and coil fractures within 5 cm of the end of the anchor sleeve. Please see Figure 1 below.

These fractures have been entered into Medtronic's CAPA system and investigations are ongoing. To date, there have been no design or significant manufacturing process changes as a result of these investigations. If our continued analysis identifies the need for future design or manufacturing changes, these changes will be fully assessed and all appropriate submission to regulatory agencies will be made.

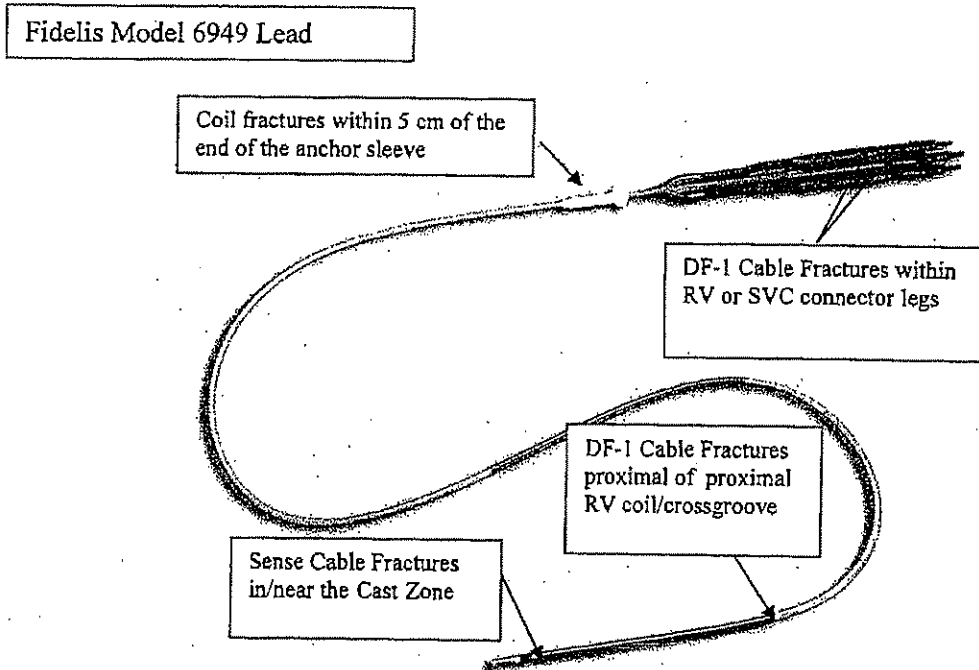


Figure 1

Note: Models 6930 and 6931 does not contain an SVC coil

Attachment 2 of this response includes a recent communication sent to physicians regarding Sprint Fidelis Leads as well as a recent communication to the Minneapolis District Office pertaining to this physician communication.

**4b)** The CAPA investigations and actions in response to question 4a apply to the entire Fidelis lead family, including models 6930, 6931, 6948 and 6949.

**4c)** A Product Performance Investigation was initiated with manufacturing to investigate and address this field event. The manufacturing process was also reviewed to ensure that the proper instructions, as well as verification and inspection points are in place. This specific mislabeling incident was addressed with operators to promote awareness of the importance of adhering to procedures for operations and inspection.

Disclaimer:

**Submission of information by Medtronic under the Medical Device Reporting regulation does not constitute an admission that the devices have malfunctioned or that there is any causal connection between the performance of the device and any injury that may have occurred. This statement should be included with any information or report disclosed to the public under the Freedom of Information Act.**

If you have any additional questions about this event or any other MDR report, please contact me directly at (763) 505-7841. You may also FAX further inquiries to (763) 505-7878.

Sincerely,



Brandy L. Corneil  
Sr. MDR Manager  
Cardiac Rhythm Management Business

cc: Megan Moynahan  
Nicole Wolanski

**Attachment 1 (Reference Question 3)**

<i>Type of Report and Reference Number</i>	<i>FDA Report Number</i>	<i>Internal Reference Number</i>	<i>Status of Analysis</i>	<i>Analysis Summary</i>
<b>A. Voluntary MedWatch</b>				
MW1040340 - LFJ056669V	2649622-2006-01080	E684170	The lead was capped. Lead not returned.	Not applicable
MW1037213 - LFJ021113V	2649622-2006-00181	E658471	MDR report 2649622-2006-00181 including analysis summary submitted 10-JAN-2006	LFJ021113V No anomalies found; proximal segment returned for analysis.
MW1041870 - LFJ069590V	2649622-2006-01516	E689306	Additional information was received. A physician's report states the lead was replaced due to noise, inappropriate therapy, apparent fracture, secondary to subclavian crush. Lead not returned. Supplemental report submitted 10_MAR-2007.	Not applicable
MW1040889 - LFJ026628V	2649622-2007-00031	E693514	MDR report 2649622-2007-00031 including analysis summary submitted 10-JAN-2007	LFJ026628V; Proximal conductor fractured; full lead returned for analysis.
<i>MW1041871 - LFJ028V (INCOMPLETE S/N)</i>	<i>Possible FDA Report Number 2649622-2006-01446</i>	<i>POSSIBLE EVENT # E686814</i>	<i>MDR report 2649622-2006-01446 submitted 10-Nov-2006 The lead was not returned for analysis</i>	<i>Not applicable</i>
MW1041872 - LFJ041110V	2649622-2006-01067	E680819	MDR report 2649622-2006-01067 including analysis summary submitted 10-SEP-2006	LFJ041110V The proximal cable and the right ventricle (RV) cable were fractured under the RV coil; full lead returned and analyzed.
MW1041873 - LFJ036021V	No MDR #	E708958	MDR report to be submitted 10-MAY-2007	LFJ036021V Proximal conductor was fractured; full lead was returned for analysis.
MW1041874 - LFJ010404V	2649622-2006-01066	E680817	MDR report 2649622-2006-01066 including analysis summary submitted 10-SEP-2006	LFJ010404V Distal conductor fractured; full lead returned and analyzed.
MW1041885 - LFJ010405V	No MDR #	E708957	MDR report to be submitted 10-MAY-2007	LFJ010405V Proximal conductor fractured; full lead analyzed.
<b>B. User Facility</b>				
4501930000-2006-8007 - LFJ039346V	2649622-2006-01299	E685608	MDR report 2649622-2006-01299 including analysis summary submitted 10-SEP-2006	LFJ039346V Proximal conductor fractured; full lead returned for analysis.
4500680000-2007-0002 - LFJ035665V	2649622-2007-00070	E695193	The lead was replaced. Lead not returned.	Not applicable

Attachment 1 (Reference Question 3), Continued

C: Manufacture				
2649622-2006-00806	2649622-2006-00806	E678451	Supplemental report submitted 10_NOV-2006.	LFJ137308V Defib conductor fracture (overstress); full lead returned for analysis. The fracture was most likely the result of implant/explant damage.
2649622-2006-00987	2649622-2006-00987	E678555	The lead was explanted. Lead not returned.	Not applicable
2649622-2006-01582	2649622-2006-01582	E691079	Supplemental report submitted 10_MAR-2007.	LFJ148031V No anomalies found; full lead was returned for analysis.
2649622-2006-01587	2649622-2006-01587	E691101	Supplemental report submitted 10_MAR-2007.	No anomalies found; full lead returned. Analysis found there is only one set of setscrew marks on one of the pins, and it is too proximal. The lead was not fully inserted into the device.
2649622-2006-01624	2649622-2006-01624	E691810	Supplemental report submitted 10_JAN-2007.	LFJ057119V Proximal conductor fractured; full lead analyzed
2649622-2006-01717	2649622-2006-01717	E697145	Supplemental report submitted 10_JAN-2007.	LFJ152198V No anomalies found; full lead was returned for analysis.
2649622-2006-01718	2649622-2006-01718	E697149	Supplemental report submitted 10_JAN-2007.	LFJ007151V No anomalies found; proximal segment analyzed; proximal segment returned for analysis.



# Medtronic

Medtronic, Inc.  
Cardiac Rhythm Management  
7000 Central Avenue NE  
Minneapolis, MN 55432

March 21, 2007

Re: Physician Information - Sprint Fidelis lead

Dear Doctor,

Medtronic has received reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their centers with Sprint Fidelis leads. While current overall Sprint Fidelis performance is consistent with other leads, Medtronic is actively investigating these reports, has reviewed them with our Independent Physician Quality Panel, and would like to share what we know at this time.

Through detailed assessment of reported fractures, we have identified two primary locations where conductor fractures have occurred: 1) distal portion of the lead and 2) near the anchoring sleeve tie down. The distal conductor fractures affect the anode (ring electrode) and fractures that occur around the anchoring sleeve affect the cathode (helix tip electrode). Fractures at both locations appear to present clinically as over-sensing, increased interval counts and inappropriate shocks. Medtronic has worked closely with physicians who have experienced fractures and conducted significant bench testing in an attempt to reproduce the fractures and identify root cause. At this point, our investigation suggests that variables within the implant procedure may contribute significantly to these fractures.

For distal conductor fractures, our investigation has identified severe bending or kinking of the distal end of the lead over the lead body while passing through tortuous vasculature as a significant contributing factor. If the lead is severely bent or kinked at the distal end, the conductor may be compromised such that the conductor may fracture after implant due to chronic fatigue from natural cardiac motion. The venous structure or pathway, venous access location, length of introducer sheath and lead insertion force are all factors that may contribute to severe bending or kinking of the lead. Medtronic recommends avoiding severe bending or kinking of the lead during implantation. If you encounter excessive resistance resulting in severe bending or kinking while advancing the lead, please remove the lead and return it to Medtronic.

For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area. We are still investigating and actively partnering with physicians to better understand this type of fracture. If excessive kinking or bending is observed during lead suturing and/or pocket formation, Medtronic recommends the lead be re-sutured and/or the pocket reassembled per guidelines in the Medtronic lead implant manual. In addition, positioning the anchoring sleeve against or near the vein may be helpful.

Sprint Fidelis lead models 6949, 6948, 6931, and 6930 were market released in the U.S. and internationally in September and October 2004. Performance of model 6949, the Sprint Fidelis lead currently followed in our System Longevity Study, indicates survival is 98.9% at two years. Sprint Fidelis 6949 performance based on return product analysis shows 99.86% chronic fracture-free survival at two years. Both evaluation methods suggest performance is in line with other Medtronic leads (see relative Medtronic performance data on the following page) and consistent with lead performance publicly reported by other manufacturers.

Medtronic is committed to ensuring the highest standards of product reliability. As we learn more, we will share additional information and technical guidance through our sales and technical representatives. If you have questions or concerns, please contact your Medtronic Representative or Medtronic Technical Services at 1-800-723-4636 (US).

Sincerely,

Reggie Groves  
Vice President, Quality and Regulatory  
Medtronic Cardiac Rhythm Disease Management  
Medtronic, Inc.

**Relative Performance of Sprint Fidelis 6949<sup>1</sup> vs. other Medtronic Leads**

Sprint Fidelis is enrolled in Medtronic's System Longevity Study which tracks chronic lead performance. At this time, we have enrolled 487 model 6949 leads in this study with 6,156 cumulative months of follow up. Results indicate survival is 98.9% at two years based on complications occurring beyond 30 days of implant. The following table summarizes data from Medtronic's System Longevity Study comparing the Sprint Fidelis lead with Sprint and Sprint Quattro:

**System Longevity Study**

Lead Model	Survival at 2 years
Sprint (6945)	99.1%
Sprint Quattro (6947)	99.3%
Sprint Fidelis (6949)*	98.9%

While Medtronic believes the most accurate method to assess lead performance is the System Longevity Study, we recognize the number of Sprint Fidelis leads followed to date in the System Longevity Study is not sufficient to be used as the sole means of gauging overall performance. Therefore, we have also examined the chronic fracture performance of this lead through Returned Product Analysis. The Sprint Fidelis lead appears to perform in line with other Medtronic leads in the market:

**Returned Product Analysis**

Lead Model	Chronic Fracture-Free Survival at 2 years
Sprint (6945)	99.92%
Sprint Quattro (6947)	99.94%
Sprint Fidelis (6949)*	99.86%

\* Due to the small implant sample size of Sprint Fidelis models 6948, 6931, and 6930, the System Longevity Study and Returned Product Analysis data is based on Sprint Fidelis 6949 leads only.

**From:** Holgers, Mike  
**Sent:** Thursday, March 29, 2007 10:34 AM  
**To:** 'Zuroski, Kristine E'

**Attachments:** FidelisLetter31607.pdf  
Kristine

This e-mail is to provide you a copy of a letter Medtronic has recently sent to physicians pertaining to conductor fractures of the Medtronic Sprint Fidelis Leads observed by a limited number of implanting physicians.

We wish to maintain clear and open communication with our customers and FDA regarding the performance of our products. Although we believe that this communication to physicians does not fall under the definition of a recall or correction under Part 7, Medtronic is providing this letter to the FDA Minneapolis District Office as a courtesy.

Attached, please find a copy of the letter provided to Fidelis Lead implanting and follow-up physicians.

As indicated in the attached letter, the Fidelis leads are performing in line with other Medtronic and competitive high voltage leads. This communication to physicians does not require submission to the FDA under Part 806 because this letter is not intended to reduce a risk to health posed by the device or remedy a violation of the act caused by the device. The Fidelis Leads are not in violation of the Act.

Additional rationale for the decision that this communication to physicians does not require submission to the FDA under Part 806 is as follows:

- This letter was sent to Fidelis physicians in response to reported conductor fractures from a limited and small number of physicians. Most physicians have not experienced a higher than expected rate of conductor fractures.
- This letter provides physicians System Longevity Study and Returned Product Analysis performance data that is similar to data distributed in the Medtronic Product Performance Report published twice a year.
- This letter does not provide any new instructions to the physician, but provides additional detail on certain failure modes and reminds them the importance of following our defined implant instructions. Our reminders pertaining to the implant procedure contained in this letter are consistent with our approved labeling.

If you have any questions, please contact me at 612-961-4148.

Thank you.

Mike Holgers  
Director Regulatory Compliance  
CRDM  
Medtronic Incorporated



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Minneapolis District Office  
Central Region  
212 Third Avenue South  
Minneapolis, MN 55401-1999  
Telephone: (612) 334-4100  
FAX: (612) 334-4134

November 01, 2007

William A. Hawkins,  
President and Chief Executive Officer  
Medtronic, Inc.  
710 Medtronic Parkway  
Mailstop LC400  
Minneapolis, Minnesota 55432-5604

RE: Recall Numbers Z-0067-2008 thru Z-0070-2008

Dear Mr. Hawkins:

You should be in receipt of a letter from Daniel G. Schultz, M.D., Director, FDA Center for Devices and Radiological Health, dated October 16, 2007, notifying you of the Class I recall classification on Medtronic Sprint Fidelis Leads models 6930, 6931, 6948 and 6949, due to potential lead fractures which have a reasonable probability to cause serious adverse health consequences, including death.

Our evaluation indicates that this recall should be conducted to the physician level and that Level A effectiveness checks should be conducted by your firm. Level A effectiveness checks are to be conducted at 100% of your consignees to verify that all consignees have received notification about the recall and have taken appropriate action.

In addition to your recall efforts, it is equally important to assure that all returned or undistributed merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped.

Our experience in similar situations has shown that, the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse. We, therefore, urge you to immediately begin making plans to destroy the product or recondition it to bring it into compliance with the law.

We request that you advise us within ten (10) days of the steps you have taken or will take to ensure the recalled product is properly inventoried and maintained to prevent unintended use or shipment, and provide your proposed method of disposition of the returned goods and your undistributed stock.

In addition, we request you submit to our Minneapolis District Office a recall status report at monthly intervals, beginning the month of December, until completion of the recall. If you have completed your recall actions at this time, you will only need to send one summary report. The recall status report should contain the following information:

1. Number of consignees notified of the recall, and date and method of notification.
2. The number of consignees responding to the recall communication.
3. Number of consignees that did not respond.
4. The number of consigned devices retrieved from hospitals or other consignee inventories, and the quantity of product accounted for.
5. Date, number, type (telephone, visit, etc.) and results of effectiveness checks that were made.



6. The estimated time frame for completion of the recall, or when the recall was completed.
7. Amount of the product on hand at your firm when the recall began, and the disposition of this product.
8. Corrective actions taken to prevent recurrence of the situation.
9. Number and summary of complaints received about lead fractures.

Address these periodic recall status reports to Kristy Zuroski, Recall & Emergency Coordinator at the Minneapolis District Office. Information indicated as needed in items 7-9 is for closing the recall, and need only be supplied in your final report.

Our judgment, regarding the effectiveness of the recall, will largely be based upon your implementation of the guidelines addressed in the FDA "Enforcement Policy" 21 CFR part 7, and "Methods for Conducting Recall Effectiveness Checks". Please be advised that failure to conduct an effective recall could result in seizure of the violative product in commerce, or other legal sanctions under the Food, Drug & Cosmetic Act.

Your response to this letter should be addressed to W. Charles Becoat, District Director.

Your cooperation in this matter is obviously important for the protection of the general public.

Sincerely,

*H. Tomblawski for:*

W. Charles Becoat  
Director  
Minneapolis District

Enclosure

cc: Michael G. Holgers  
Director of CRDM Compliance  
Medtronic Cardiac Rhythm Disease Management  
7000 Central Avenue N.E.  
Minneapolis, Minnesota 55432-3576



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration  
Office of Device Evaluation  
9200 Corporate Boulevard  
Rockville, MD 20850

October 14, 2008

Congress of the United States  
House of Representatives  
Representative John D. Dingell  
2328 Rayburn House Office Building  
Washington, DC 20515

Dear Mr. Dingell:

This letter seeks your urgent intervention because serious misconduct by managers of the U.S. Food and Drug Administration (FDA) at the Center for Devices and Radiological Health (CDRH) is interfering with our responsibility to ensure the safety and effectiveness of medical devices for the American public and with FDA's mission to protect and promote the health of all Americans. Managers at CDRH have failed to follow the laws, rules, regulations and Agency Guidance to ensure the safety and effectiveness of medical devices and consequently, they have corrupted the scientific review of medical devices. This misconduct reaches the highest levels of CDRH management including the Center Director and Director of the Office of Device Evaluation (ODE).

[REDACTED] physicians and scientists [REDACTED] at CDRH have already sought intervention from the FDA Commissioner. The physicians and scientists [REDACTED] [REDACTED] are responsible for ensuring the safety and effectiveness of all [REDACTED] devices before they are used on the American public. The devices we regulate are crucial and fundamental to medical practice [REDACTED] [REDACTED] devices constitute a substantial [REDACTED] cost to the [REDACTED] American health care system with more than 500 million adult and pediatric [REDACTED] procedures performed every year in the United States.

It is crucial for FDA to regulate medical devices based on rigorous science. As stated in the November 2007 FDA Science Board Report<sup>1</sup> entitled "FDA Science and Mission at Risk":

<sup>1</sup> Available at [http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b\\_02\\_00\\_index.html](http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html)



“A strong Food and Drug Administration (FDA) is crucial for the health of our country. The benefits of a robust, progressive Agency are enormous; the risks of a debilitated, under-performing organization are incalculable. The FDA constitutes a critical component of our nation’s healthcare delivery and public health system. The FDA, as much as any public or private sector institution in this country, touches the lives, health and wellbeing of all Americans and is integral to the nation’s economy and its security. The FDA’s responsibilities for protecting the health of Americans are far-reaching. ... The FDA is also central to the economic health of the nation, regulating approximately \$1 trillion in consumer products or 25 cents of every consumer dollar expended in this country annually. The industries that FDA regulates are among the most successful and innovative in our society, and are among the few that contribute to a positive balance of trade with other countries. The importance of the FDA in the nation’s security is similarly profound. ... Thus, the nation is at risk if FDA science is at risk.”

There is extensive documentary evidence that managers at CDRH have corrupted and interfered with the scientific review of medical devices. The scientific review of medical devices is required to work as follows: FDA clinical and scientific experts (“FDA experts”) review submissions based on the best available scientific information and in accordance with the Food Drug and Cosmetic Act, the Code of Federal Regulations and Agency Guidance documents (when such Guidance documents exist for a particular device or category of devices). FDA experts give their best scientific judgments, opinions and conclusions regarding safety and effectiveness of medical devices and make corresponding regulatory recommendations. These form the scientific and regulatory basis for managers at FDA to make final regulatory decisions (i.e., clearance or approval of medical devices). While managers can disagree with FDA experts, they cannot order, force or otherwise coerce FDA experts to change their scientific judgments, opinions, conclusions or recommendations. In accordance with the law, if managers at FDA disagree with FDA experts, managers must document their disagreements in official Agency records, must scientifically justify any contrary judgments, opinions, conclusions or recommendations and must take personal responsibility for their final regulatory decisions. The review process is well described in long existing Agency Guidance.<sup>2</sup>

The law requires that qualified experts make safety and effectiveness determinations based on valid scientific evidence. Managers at CDRH with no scientific or medical expertise in [REDACTED] devices, or any clinical experience in the practice of medicine [REDACTED], have ignored serious safety and effectiveness concerns of FDA experts and have ignored scientific regulatory requirements. To avoid accountability, these managers at CDRH have ordered, intimidated and coerced FDA experts to modify their scientific reviews, conclusions and recommendations in violation of the law. Furthermore, these managers have also ordered, intimidated and coerced FDA experts to make safety and effectiveness determinations that are not in accordance with scientific regulatory requirements, to use unsound evaluation methods, and accept clinical and technical data that is not scientifically valid nor obtained in accordance with legal requirements, such as obtaining proper informed consent from human subjects. These same

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<sup>2</sup> Available at <http://www.fda.gov/cdrh/g93-1.html>.

managers have knowingly avoided and failed to properly document the basis of their decisions in official Agency records.

Under the banner of regulatory "precedent," managers at CDRH have demanded that physicians and scientists review regulatory submissions employing methods, and accepting evidence and conclusions, that are not scientifically proven and clinically validated. These demands appear to be based on the misguided notion that because flawed methods, evidence and conclusions were used or accepted in the recent or even the remote past, we must continue to blindly and knowingly accept these flawed methods, evidence and conclusions and continue to use them as the basis for regulatory recommendations. Such invalid regulatory "precedent" goes against current scientific and clinical evidence. Rather than remedy past regulatory or scientific errors after they come to light, and rather than applying the best and latest scientific knowledge and methodology, these managers at CDRH knowingly continue to make the same regulatory and scientific mistakes over and over again. Rather than recall, re-evaluate or otherwise deal with potentially unsafe or ineffective devices that are already on the market, these managers at CDRH continue to approve more devices of the same kind in a non-transparent and non-scientific manner. This is especially true of the 510(k) program but also applies to the PMA program as well as the advice and guidance given to manufacturers before they make regulatory submissions. The practices described above represent an unwarranted risk to public health and a silent danger that may only be recognized after many years.

When physicians and scientists have objected to the management practices described above, managers at CDRH have engaged in reprisals and ignored these critical concerns. FDA physicians and scientists therefore contacted the Office of the Commissioner:

- On May 31, 2008, [REDACTED] FDA physicians and scientists [REDACTED] wrote to the FDA Commissioner, Dr. Andrew von Eschenbach (See attached letter).
- The Commissioner immediately asked Mr. William McConagha, the Assistant Commissioner for Integrity and Accountability, to begin a full investigation.
- Since early June 2008, FDA physicians and scientists have met with Mr. McConagha numerous times and have facilitated his investigation by providing written documentary evidence including internal emails, reviews, memos, meeting minutes, etc.
- Mr. McConagha has characterized the documentary evidence as "compelling," "convincing" and "sufficient" to justify curative and disciplinary actions. As a result, the Commissioner met with the CDRH Director in August.
- On September 3, 2008, [REDACTED] FDA physicians and scientists [REDACTED] met with the Director of CDRH in the presence of representatives from the Commissioner's Office. At the request of Mr. McConagha, the FDA physicians and scientists presented the issues and documentary evidence to the Director of CDRH (See attached presentation).

- The Director of CDRH then conducted his own investigation and concluded that we, FDA physicians and scientists, need to “move forward,” thus allowing managers to avoid and evade any accountability and without taking any curative or disciplinary actions whatsoever. The Director of CDRH has further aggravated the situation by knowingly allowing a continuation of management reprisals. These reprisals now include removal and threatened removal of physicians and scientists [REDACTED] [REDACTED] [REDACTED] as well as illegal and improper employee performance evaluations.
- On September 29, 2008, [REDACTED] FDA physicians and scientists wrote a second letter to Dr. von Eschenbach (see attached letter).

To date, despite involvement by the Commissioners Office, there has been enormous internal resistance from entrenched managers at CDRH including the Center Director and the Director of ODE. These managers seem far more concerned about ensuring their current positions and protecting and promoting their own careers and those of their cronies, than they are about ensuring the safety and effectiveness of medical devices and protecting and promoting the health of all Americans. CDRH managers prefer to employ regulation-based “pseudo-science” rather than science-based regulation.

It is evident that managers at CDRH have deviated from FDA’s mission to identify and address underlying problems with medical devices before they cause irreparable harm, and this deviation has placed the American people at risk. Given the large number of [REDACTED] [REDACTED] submissions to the FDA, the complexity of the scientific and medical issues involved and the importance of [REDACTED] devices to the practice of medicine, we believe that proper regulation of [REDACTED] devices requires the establishment of a new and separate Office at FDA [REDACTED]. This Office must be staffed by expert physicians and scientists at all levels including management and must provide vision and leadership by being proactive rather than reactive, by incorporating the latest scientific and technological evidence into device evaluation, compliance and post-market surveillance, and by making all regulatory decisions in a transparent manner based on sound scientific and clinical principles. At the same time, there is a need for new legislation that modernizes the regulatory structure of the 510(k) program so that complex medical devices are not allowed onto the market without a comprehensive (or in some cases, any) clinical evaluation of their safety and effectiveness. This is especially true for [REDACTED] devices due to their markedly increased use in clinical practice and because [REDACTED] devices employ highly complex hardware and software, undergo rapid technological changes and touch the lives of so many patients on a daily basis. The current framework for medical device adverse event reporting does not work for many [REDACTED] devices [REDACTED] as the adverse effects of [REDACTED] devices are rarely detected immediately, are not transparent on an individual patient basis, and can only be prevented by a rigorous pre-market evaluation process.

FDA leaders need to re-establish the trust of the American people. Congress needs to ensure that FDA physicians and scientists can do their jobs by being allowed to follow the laws, rules and regulations without fear of reprisal, by applying the best and latest scientific knowledge and methodologies, by having an updated modern regulatory structure, and by allocating sufficient financial and other resources to FDA.<sup>1</sup> Finally, FDA leaders and Congress must restore compliance with the law, must hold accountable those managers at FDA that fail to carry out the

FDA mission to protect and promote the health of all Americans, and must protect FDA physicians and scientists so that they can protect the American public.

As the Branch of government responsible for oversight of the FDA, we urgently seek your intervention and help.

[REDACTED]

[REDACTED]

[REDACTED]



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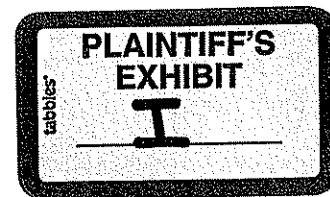
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Note: this medical device record is a supplement. The device description may have changed. Be sure to look at the [original PMA](#) to get an up-to-date view of this device.

### Premarket Approval (PMA) Database

**Trade Name** MODEL 6949 AND 6931 LEADS  
**Classification Name** [Defibrillator, Automatic Implantable Cardioverter](#)  
**Generic Name** Transvenous, Steroid Eluting, Quadripolar, Active Fixation, Pace/Sense Ventricular Lead  
**Applicant** MEDTRONIC VASCULAR  
**PMA Number** P920015  
**Supplement Number** S029  
**Date Received** 11/06/2003  
**Decision Date** 06/08/2004  
**Product Code** LWS [[Search Manufacturers for LWS](#)]  
**Advisory Committee** Cardiovascular  
**Supplement Type** Normal 180 Day Track  
**Supplement Reason** Change Design/Components/Specifications - Specifications  
**Expedited Review Granted?** No  
**Approval Order Statement** Approval for the addition of a polyurethane overlay.



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### Premarket Approval (PMA) Database

<b>Trade Name</b>	MODEL 6948 AND 6930 LEADS
<b>Classification Name</b>	<u>Defibrillator, Automatic Implantable Cardioverter</u>
<b>Generic Name</b>	Transvenous, Steroid Eluting, Quadripolar, Active Fixation, Pace/Sense Ventricular Lead
<b>Applicant</b>	MEDTRONIC VASCULAR
<b>PMA Number</b>	P920015
<b>Supplement Number</b>	S030
<b>Date Received</b>	12/22/2003
<b>Decision Date</b>	06/08/2004
<b>Product Code</b>	LWS [ <a href="#">Search Manufacturers for LWS</a> ]
<b>Advisory Committee</b>	Cardiovascular
<b>Supplement Type</b>	Normal 180 Day Track
<b>Supplement Reason</b>	Change Design/Components/Specifications - Specifications
<b>Expedited Review Granted?</b>	No
<b>Approval Order Statement</b>	Approval for the addition of a polyurethane overlay.

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### Premarket Approval (PMA) Database

**Trade Name** MEDTRONIC SPRINT FIDELIS LEADS MODELS,6949,6948,6931,6930  
**Classification Name** [Defibrillator, Automatic Implantable Cardioverter](#)  
**Generic Name** Transvenous, Steroid Eluting, Quadripolar, Active Fixation, Pace/Sense Ventricular Lead  
**Applicant** MEDTRONIC VASCULAR  
**PMA Number** P920015  
**Supplement Number** S032  
**Date Received** 09/02/2005  
**Decision Date** 12/01/2005  
**Product Code** LWS [ [Search Manufacturers for LWS](#) ]  
**Advisory Committee** Cardiovascular  
**Supplement Type** 135 Review Track For 30-Day Notice  
**Supplement Reason** Process Change: Manufacturing  
**Expedited Review Granted?** No  
**Approval Order Statement** Approval to change the aeration time following sterilization of the sprint fidelis leads.

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### Premarket Approval (PMA) Database

<b>Trade Name</b>	MEDTRONIC SPRINT FIDELIS LEAD
<b>Classification Name</b>	<a href="#">Defibrillator, Automatic Implantable Cardioverter</a>
<b>Generic Name</b>	Transvenous, Steroid Eluting, Quadripolar, Active Fixation, Pace/Sense Ventricular Lead
<b>Applicant</b>	MEDTRONIC VASCULAR
<b>PMA Number</b>	P920015
<b>Supplement Number</b>	S037
<b>Date Received</b>	05/15/2007
<b>Decision Date</b>	07/03/2007
<b>Product Code</b>	LWS [ <a href="#">Search Manufacturers for LWS</a> ]
<b>Advisory Committee</b>	Cardiovascular
<b>Supplement Type</b>	Real-Time Process
<b>Supplement Reason</b>	Change Design/Components/Specifications - Other
<b>Expedited Review Granted?</b>	No

**Approval Order Statement** Approval for design and manufacturing changes to improve the df-1 leg strength and handling characteristics of sprint fidelis leads.

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**Premarket Approval (PMA) Database**

**Trade Name** MEDTRONIC SPRINT LEADS  
**Classification Name** [Defibrillator, Automatic Implantable Cardioverter](#)  
**Generic Name** Transvenous, Steroid Eluting, Quadripolar, Active Fixation, Pace/Sense Ventricular Lead  
**Applicant** MEDTRONIC INC.  
**PMA Number** P920015  
**Supplement Number** S038  
**Date Received** 09/12/2007  
**Decision Date** 02/06/2008  
**Product Code** LWS [ [Registered Establishments with LWS](#) ]  
**Advisory Committee** Cardiovascular  
**Supplement Type** 135 Review Track For 30-Day Notice  
**Supplement Reason** Process Change: Manufacturing  
**Expedited Review Granted?** No

**Approval Order Statement** Approval for changing the molding vendor and molding process parameters for the is-1 connector sleeve component for sprint lead models 6930, 6931, 6945, 6947, 6948, 6949, and 6944.

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