TABLE OF CONTENTS

SUMMARY

Inspection of this cardiovascular medical device manufacturer was conducted as part of Premarket Approval inspection assignment #891086 for P060039, submitted by Medtronic Inc for the Attain StarFix™ Model 4195 Lead. This inspection also was a follow-up to Class I Recall Z-0067-2008 and the last inspection, in which a FDA-483, Inspectional Observations was issued to the firm. Guidance in Compliance Program 7383.001, Medical Device Premarket Approval and Postmarket Inspections (FY94/95) and Guidance in Compliance Program 7382.845, Inspection of Medical Device Manufacturers was used.

The previous inspection was conducted on 6/5/2006 to 7/14/2006. It was prompted by MIN-DO workplan and the Implantable Cardioverter Defibrillator (ICD) assignment from CDRH. Also performed was a post PMA inspection on the Select Bipolar Ventricular Pacing Lead Model 3830, a CDRH directed coverage of ICD related MDR's from OSB, and a follow up to Concerto ICD related concerns regarding its new RF Telemetry feature called Telemetry C. A 3-item FDA FORM 483 was issued with two observations relating to the CAPA system and one for the failure to MDR an ICD malfunction.

The current inspection was a Premarket Approval Inspection Assignment #891086 for P060039, submitted by Medtronic Inc for the Attain StarFix™ Model 4195 Lead. This inspection also was a follow-up to Class I Recall Z-0067-2008 and the last inspection, in which a FDA-483, Inspectional Observations was issued to the firm. A one-item FDA-483 was issued to the firm for CAPA procedures not being followed. Four verbal observations were made to the firm for assuring recalls are being done timely, creating a procedure or written process for the (b) (4), making it clear how your Process Control Device (PCD) is harder to sterilized than your product, and that now that you have used CARELINK data in your analysis that it should be used in other similar situations.

No samples were collected during this inspection.

ADMINISTRATIVE DATA

Inspected firm:	Medtronic Inc. Cardiac Rhythm Disease Management
Location:	8200 Coral Sea Street NE Mounds View, MN 55112
Phone:	763-526-0000
FAX:	
Mailing address:	8200 Coral Sea Street NE Mounds View, MN 55112
Dates of inspection:	10/18/2007, 10/19/2007, 10/23/2007, 10/24/2007, 10/25/2007,

	10/26/2007, 10/29/2007, 11/5/2007, 11/6/2007, 11/7/2007, 11/9/2007, 11/14/2007, 11/15/2007, 11/19/2007, 11/20/2007, 11/26/2007, 11/27/2007, 11/28/2007, 11/29/2007, 12/3/2007, 12/10/2007, 12/11/2007, 12/13/2007, 12/14/2007, 12/17/2007, 12/18/2007, 12/21/2007
Days in the facility:	27
Participants:	Billi Jo M. Johnson, Investigator
	Janis R. Armendariz, Investigator

Upon arrival at the firm on 10/18/07, we, Investigator Billi Jo M. Johnson, and Investigator Janis R. Armendariz, displayed our credentials and issued a Form FDA-482, Notice of Inspection, to Mr. Subu (nmi) Mangipudi, Director Product Vigilance and Reliability. Mr. Mike Holgers, Director CRDM Compliance, was not available at the opening meeting but did join the inspection on 10/19/07. Pat Mackin, Executive Vice President of the Cardiac Rhythm Disease Management (CRDM) was not available during the inspection.

I, Billi Jo M. Johnson, was accompanied by Investigator Armendariz 10/18-19, 23-26, 29, 11/5-7, 9, 14-15, 19-20, 27-29, and at the closing meeting on 12/21/07. This report was written by Investigator Johnson with review and input from Investigator Armendariz.

HISTORY

Medtronic Inc. was started in 1949 and is incorporated in MN. Medtronic Cardiac Rhythm Disease Management (CRDM) is one division of Medtronic, Inc. CRDM manufactures and markets implantable pacemakers, defibrillators, cardiac ablation catheters, monitoring and diagnostic devices, cardiac resynchronization devices, automated external defibrillators (AEDs), and the CareLink Patient Network.

This firm's registration number is 2182208 and has a status of active. Office hours are 8:00 a.m. – 5:00 p.m. Monday through Friday. The most responsible member at this site is Mr. Pat Mackin, Executive Vice President of the Cardiac Rhythm Disease Management (CRDM), and he is located at the address listed in the Administrative Data section above. William Hawkins, III is Medtronic's CEO and is located at 710 Medtronic Parkway, Minneapolis, MN 55432.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Pat Mackin, Executive Vice President of the Cardiac Rhythm Disease Management (CRDM) branch of Medtronic Inc, reports to Mr. Hawkins. See **Exhibit #1** or and CRDM Organization Chart.

William Hawkins, III, CEO of Medtronic Inc, is located at Medtronic headquarters located at 710 Medtronic Parkway, Fridley, MN 55432. Mr. Hawkins is ultimately the most responsible person at Medtronic Inc.

Reggie Groves, VP CRDM Quality & Regulatory, has responsibility for the quality and regulatory organization at CRDM. He reports to Mr. Mackin. See **Exhibit #2** for CRDM Quality & Regulatory Organization Chart.

Sara Rottunda, Director Quality Systems Solutions, is responsible for the quality audit division and is the firm's management representative. She reports to Mr. Groves.

Michael G. Holgers, Director, CRDM Compliance, has responsibility for CRDM compliance activities; he is the main contact for FDA at CRDM. He reports to Ms. Rottunda.

Mr. Subu Mangipudi, Director Product Vigilance & Reliability, is responsible for the quality engineers and manufacturing site quality organizations. He reports to Mr. Groves.

Mr. Tim Samsel, VP Regulatory Affairs, is responsible for all regulatory submissions at CRDM. He reports to Mr. Groves.

Mr. Pat Fuher, Sr. Director R&D Quality, has responsibility for all engineers that work on R&D projects. He reports to Mr. Groves.

Questions were also answered by Mr. Samsel, Mr. Mangipudi, Mr. Holgers, and the following:

Brandy Corneil, MDR Manager	Jim Roche, Reliability Engineer	Mike Huepenbecker, Product Development Manager 4195
Brett Broederdorf, Senior Reliability Engineer	Joe Dupay, Senior Director CRT Lead Programs	Nathan Olson, Senior Mechanical Design Engineer
Dave Schaenzer, Senior Principal Reliability Specialist	Lauren Williams, Manager Return Product Analysis	Norman Ganion, Senior Principal Auditor
Deb Loch, Product Development Manager	Lewis Werner, Senior Engineer Manager	Preston Heinz, Senior Reliability Engineer
Florence Laverny-Rafter, Senior Audit Manager	Ling Lu, Senior Pharma Quality Engineer	Scott Cundy, Senior Director CRDM Pre-Market Regulatory Affairs
Jason Hedrick, Principal Sterilization Specialist	Mark Hjelle, Senior Principal Quality Analyst CRDM Quality	Shantha Samarasinghe, Senior Principal Quality Engineer
Jim Gates, Reliability Assurance Manager	Michelle Widen, Senior Principal Quality Systems Specialist	Tom Gorka, Manager Release Systems Reliability

The first day of the inspection we were accompanied by Ms. Linda L. Lach, Director Product Development Quality CRDM Implantable Business, Mr. Subu Mangipudi, Director Product Vigilance and Reliability, and Mr. Norman Ganion, Sr. Principal Auditor CRDM. The rest of the inspection we were accompanied by Mr. Holgers or Mr. Ganion.

INTERSTATE COMMERCE AND JURISDICTION

CRDM manufactures and markets implantable pacemakers, defibrillators, cardiac ablation catheters, monitoring and diagnostic devices, cardiac resynchronization devices, AEDs, and the CareLink Patient Network. (b) (4)% of all products Medtronic sells are sold into interstate commerce.

The PMA inspection dealt with the Attain StarFix™ Model 4195 Lead and the follow-up to Class I Recall Z-0067-2008 dealt with the Sprint Fidelis™ Leads 6949, 6948, 6931, and 6930. The Attain is a steroid-eluting left ventricular lead for pacing and sensing via the cardiac vein. See **Exhibit #3** for the Attain StarFix 4195 Technical Manual. The Fidelis leads are Steroid eluting, tripolar, ventricular leads with tined tip and right ventricular (RV) defibrillation coil electrode. It is designed for pacing, sensing, cardioversion, and defibrillation therapies. See **Exhibit #4** for a product brochure for the Fidelis Leads.

MANUFACTURING/DESIGN OPERATIONS

The topics under this heading were reviewed under the PMA portion of this inspection. Production and Process Controls were not covered in this inspection. All production of leads is completed in Puerto Rico. A separate inspection was conducted at that site for the Attain Lead PMA.

Management Controls

I reviewed the firms Quality Manual, Business and Quality Management Manual, 8/31/07, Version 8 (**Exhibit #5**), and Quality Policy. The firm's management representative is noted on the Organization Chart in **Exhibit #2**. Management Reviews are being held as required by their procedures. I also reviewed the Internal Audit Procedure and internal audit schedules from FY07 and FY08. No observations were made during this review.

Design

The design process covered in this inspection was for the Attain StarFix™ Model 4195 Lead. Design control is conducted in (b) (4)

(b) (4) . Refer to Therapy Delivery Product Development Guidance Procedure Overview, THD.0401.0007, Version 2.0 (**Exhibit #6**) for a flow diagram of the process.

I reviewed the firm's device history file for the Attain StarFix Lead. This is a steroid-eluting left ventricular lead for pacing and sensing via the cardiac vein. In this review I asked for design inputs and was given the following documents. First was **Exhibits #7 & 8**, which are reviews conducted on design inputs. Second was the firm's product specification for both the overall silicone and polyurethane leads (**Exhibit #9**). (b) (4) No observations were made during this review. They also have a product specification that is specific to the Attain StarFix, this is **Exhibit #10**. The product specifications along with the product drawing (**Exhibit #11**), are said to contain all product inputs for the device.

We also discussed what documentation the firm had on how their design outputs met their inputs. They supplied me with the Design Assurance Protocol and Report (**Exhibits #(12 & 13)**) and stated that the validation report having passed will show that all inputs were met. At this time they also supplied me with the Model 4195 In Vitro Test Regulatory Summary Report (**Exhibit #14**), which is an overview of all testing conducted on the device during design. This document is submitted with the PMA as a quick reference guide to the design testing. Finally Mr. Roche supplied a document that tied together all documents related to the design validation report, which also discussed how inputs were met (**Exhibit #15**).

We next discussed the Design Review document (**Exhibit #16**) and the FMEA for the lead, which is **Exhibit #17**. No observations were made during the review of the design history file for the Attain StarFix lead.

Sterilization

The sterilization process covered in this inspection was the design validation for the Attain StarFix™ Model 4195 Lead which is the (b) (4) sterilization process. This is (b) (4) sterilizers. (b) (4) . For validation of the cycle the firm is following ANSI/AAMI/ISO 11135, ANSI/AAMI/ISO 10993-7, EN556, AAMI TIR 19:1998, and EN 550. The sterilization of the product manufactured in Puerto Rico is done (b) (4) sterilization cycle, which was verified there. That process was not reviewed in this inspection.

Validation production units were sent packaged and labeled to (b) (4) for sterilization. After sterilization they are returned for validation testing purposes. The sterilization process was validated

to a [redacted] (b) (4) [redacted] Revalidation is scheduled to be conducted (b) (4). Refer to **Exhibits #18-20** for the Sterilization Strategy, Protocol, and Report. One verbal observation was made during this review. Upon reviewing the Process Control Device (PCD) data I explained that it was not clearly stated that this device was harder to sterilize than the actual device being tested. Mr. Hedrick stated that the PCD was (b) (4) [redacted], but that it should be clearly stated in the validation.

COMPLAINTS/CAPA

The Complaint and CAPA processes were reviewed throughout this inspection. This section contains the information reviewed as part of the PMA process and as a follow-up to the last inspection. Specifics relating to the Fidelis recall are listed below under the section titled Fidelis Recall.

Complaints

We reviewed the firm's complaint handling procedures, Initial Complaint Review, CSS.2104.0001, Version 2.1, 1/18/07 (**Exhibit #21**) and MDR Review, CSS.2105.0001, Version 5.0, 7/23/07 (**Exhibit #22**). We assessed 85 complaint files from the last inspection to present. Complaints are taken by a centralized complaint department for all of CRDM, called the Cardiac Rhythm Disease Management Medical Device Reporting Department. This group is responsible for receiving the complaints and entering them into the complaint system (b) (4)).

Returned products from complaints are sent to the Product Performance Lab for testing. A quality engineer is notified of the need for complaint investigation. This engineer will make the determination if a CAPA is warranted. An MDR specialist also reviews each complaint for adverse events. Trending is completed by product, by MDR reportable, and by Product Performance Codes also known as failure codes. As a follow-up to Observation 3 in the last inspection, we did not note any complaints that when required to file an MDR the firm failed to do so. No observations were made during this review.

CAPA

We reviewed the corrective action procedures, Corrective and Preventive Action, GP.1401, Version 6.0, 09/28/07 (**Exhibit #23**), and Field Product Impact Assessment, CRM.1401.0002, Version 1.0, 10/5/07 (**Exhibit #24**). We then looked at 31 CAPAs from 2006-present. There were no CAPAs for the Attain StarFix Lead. As a follow-up to the last inspections Observation 1, we did not note any CAPAs that has unvalidated processes linked to them. One observation was made during this review. See Observation 1 below for more details.

A verbal observation was also made during this discussion. We noted that the larger CAPAs made reference to a "(b) (4) ". When asked what this was Mr. Hjelle stated that when a CAPA was large and encompassed many members a team was formed to assure the process was tracked and that people's time was allotted for. This team met on a regular basis. The creation of this team environment was not contained in the CAPA procedure. Meeting minutes were kept for these meetings and tasks were tracked to completion, but not all information was in the CAPA file. I explained that the actions related to a corrective action needed to be captured in the CAPA files. We discussed the need for the CAPA procedure to include the "(b) (4) " process to ensure that all elements of the process were in the files.

FIDELIS RECALL

On October 11, 2007 Medtronic CRDM decided to recall the Sprint Fidelis Leads and suspended sale and production of the leads. We reviewed the firms Field Corrective Action Policy, CQRA-004, Revision A, 9/5/2001 (**Exhibit #25**). See **Exhibit #26** for the Field Communication Plan created for the Fidelis Recall. The following information is that which relates to the Fidelis Recall.

FPIR related Complaints/MDRs

We requested a copy of all 15 death related complaints and MDRs that were referenced in the FPIR. These are attached as **Exhibits #27-41**. The five that were determined to be most likely related to the lead fractures by their Medical Director are E716070, E691064, E705409, E736594, and E734526 (**Exhibits #27-31**). The firm's Medical Director Dr. David Steinhaus reviewed all the complaints along with strip charts and ECGs. In his medical opinion only four deaths were likely related to the device and one death was possibly related to the device. The others were reported via MDR to be on the conservative side, even though the Medical Director did not believe the device caused the death. (b) (6) . Also attached is **Exhibit #42** for a CD which contains a Complaint Log for all Fidelis Complaints up to 10-25-2007.

2005

The Sprint Fidelis Leads were released in September 2004. CAPA 644 (**Exhibit #43**) was created on 7/27/2005 due to two Fidelis leads being returned for fractures in (b) (4) no FPIR was completed (see Observation 1). By August 2005 two additional failure modes were identified and added to the CAPA file, one for fractures in (b) (4) , and a second for fracture of (b) (4) . At this time the (b) (4) fractures were not being investigated just noted in the file. In November 2005 it was decided that the amount of time that was needed for this CAPA was large and so a separate team or (b) (4) " was created specifically to track the progress of this

CAPA. These meeting minutes are attached as **Exhibit #44**. As of the first meeting there were a total of 30 complaints logged between the three failure modes. (b) (4)

2006

In February 2006 a review of all engineering variances at both Puerto Rico and Spring Lake Park manufacturing sites was conducted. (Refer to **Exhibits #45 & 46**). There was a belief that the manufacturing process could be (b) (4) and the returned product. At the time it (b) (4), see **Exhibit #47** for a summary of the analysis that was conducted in May 2006. This review is summarized in **Exhibit #48**. (b) (4)

In May 2006 a Summary Report (**Exhibit #49**) of the fractures a(b) (4) was conducted. It was (b) (4).

(b) (4) that a root cause was found. It was noted that if the (b) (4) that could result in a fracture. Refer to **Exhibit #50** for an overview of this failure and its root causes completed in May 2006. Once this was known two major steps were taken. First was a Tech Note (**Exhibit #51**) was sent to the field, reminding them to assure that the connector was not kinked or quickly tugged because of the increase likelihood of fractures at that site. Second a PMA submission (P9200015 S27) was sent to FDA with (b) (4) to the device. The supplement was approved in June 2007.

In May 2006 a Peer Review meeting was held for all the information that was collected so far on the CAPA. **Exhibit #52** is a copy of the PowerPoint used for the review. Along with that a statistical analysis of the three failure modes was conducted in October 2006 (**Exhibit #53**), which determined (b) (4) % confidence for all fractures. In June 2006 a rationale for not completing a FPIR was conducted and is attached at **Exhibit #54**. (b) (4).

2007

In March 2007 a fourth failure mode that had been seen a(b) (4) . It was decided(b) (4) that a separate CAPA would be opened for this failure mode. See CAPA 854 (**Exhibit #55**). Investigations into this failure mode are attached as **Exhibits #56, 57, & 58**. Additional information is found in **Exhibits #59-61**, which are TIMS (Technical Information Memos).

In January the initial FPIR was started for CAPA 644. This was signed off in April 2007, see **Exhibit #62**. Revision B (**Exhibit #63**) of the FPIR was completed within a day of Revision A due to CAPA 854 not being correctly identified. Revision C (**Exhibit #64**) was completed in October 2007 with the addition of more complaints and the CareLink data. Revision D (**Exhibit #65**) was then completed seven days later when the decision to recall was decided upon. (b) (4) s, refer to **Exhibit #66** for this breakdown. **Exhibit #67** is an overview of the process that was used to obtain information from the CareLink system. (b) (4) the returned product data that was reviewed in the Lead & Accessory Product Performance Meetings. The last two meeting minutes and PowerPoint presentations are attached as **Exhibits #68 & 69**.

In March 2007 a decision was made to send out a Tech Note (**Exhibit #70**) on the issues with severe bending or kinking of the lead and how this could lead to fractures. (b) (4) Also completed in March was a timeline of the activities in CAPA 644 (**Exhibit #71**). Lastly completed in March was a new Summary Report of the(b) (4) fractures (**Exhibit #72**), which still do not have a root cause identified. A redesign of the(b) (4) was conducted and a design evaluation was conducted in August 2007 an is attached as **Exhibit #73**.

In May 2007 an effectivity check was conducted on the Tech Note sent out in July 2006 for(b) (4) fractures. **Exhibit #74** summarizes what was found in this check. Some analyses of fractures by age were conducted, but results were determined to be similar to other leads and not important to the Fidelis leads in particular. These analyses are attached as **Exhibits #75-77**.

Below is a break down of how some of the attachments listed above link to CAPA 644 and CAPA 854.

Exhibit #	***Document Title***	***Linkage to CAPA file***
Exhibit #45	Fidelis CAPA File: Process Change and Variance Review of Fidelis Models	CAPA #644, Task #2826, Attachment #7577

Exhibit #46	Fidelis CAPA File: Process Change Review of Fidelis Models	CAPA #644, Task #2826, Attachment #7578
Exhibit #47	Summary Report - CAPA #000644: Cable Fractures at (b) (4)	CAPA #644, Task #2824, Attachment #8479
Exhibit #48	Fidelis CAPA File: Process Change Review of Fidelis Models	CAPA #644, Task #2826, Attachment #7579
Exhibit #49	Summary Report - CAPA #00644: Cable Fractures in (b) (4)	CAPA #644,Task #2824, Attachment #8478
Exhibit #50	Summary Report - CAPA #00644: Cable Fractures in the (b) (4)	CAPA #644, Task #2824, Attachment #8371
Exhibit #52	Fidelis CAPA Team Project Review - Peer Review	CAPA #644, Task 4819, Attachment #12896
Exhibit #53	Interoffice Memo - Fidelis Fracture Statistical Analysis as of 1 Aug 2006	CAPA #644, Attachment #10220
Exhibit #54	Inter-Office Memo Rationale for FPIR	CAPA #644 Attachment #8728
Exhibit #56	Summary of Meeting Minutes	CAPA #854, Notes #11755
Exhibit #59	Baseline Activities	CAPA #854, Task #4389, Attachment #12227
Exhibit #60	(b) (4) TIM#3 Agenda	CAPA #854, Task #4637, Attachment #12418
Exhibit #61	Fidelis (b) (4) Team Final Technical Communication	CAPA #854, Task #4638, Attachment #12419
Exhibit #71	Interoffice Memo - CAPA 000644 Timeline	CAPA #644, Task #3880, Attachment #11379
Exhibit #72	Summary Report - CAPA #00644: Cable Fractures in (b) (4)	CAPA #644, Task #4222, Attachment #11436. Ties to ECO 02075
Exhibit #73	Design Evaluation Test Report for New Configuration of (b) (4) of Fidelis Lead Models 6930, 6931, 6948 and 6949 (b) (4)	CAPA #644, Task #4227, Attachment #12475
Exhibit #74	Memo to CAPA000644 File - DF1 Tech Note Effectivity Check	CAPA #644, Task #4225, Assignment #12023

Exhibit #75	Analysis of Fractures per Model Family by Patient Age at Time of Implant	CAPA #644, Task #4837, Attachment #12871
Exhibit #76	Analysis of Model 6949 Fractures Based on DRS/RPA and CareLink & DRS/RPA Datasets	CAPA #644, Task #4837, Attachment #12872
Exhibit #77	Analysis of Model 6949 Fractures by Patient Age at Time of Implant	CAPA #644, Task #4837, Attachment #12873

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

The FDA-483 was modified because the initial signed copy had a typographical error; it listed CAPA 000873 instead of CAPA 000783 in the last bullet point. The original and modified documents are attached. The FDA-483 was issued on 12/21/07 at the closing meeting to Sara M. Rottunda, Director Quality Systems & Compliance.

Observations listed on form FDA 483

OBSERVATION 1

The corrective and preventive action procedures addressing the investigation of the cause of nonconformities relating to product, processes, and the quality system were not implemented.

Specifically, CAPA procedure GP.1401, various revisions from 2006 to present, requires a FPIR to be completed during the investigate stage of the CAPA process, when a risk assessment is needed. The FPIR procedure RCC.1401.0002, various revisions from 2006 to present, states that the FPIR or Field Product Impact Report, is completed when a CAPA request has the potential to affect clinical or market-released product.

- The following CAPAs, which affect clinical or market-released product, do not include further documentation of the FPIR process:
  - CAPA 000834
  - CAPA 000842
  - CAPA 000876
  - CAPA 000888
  - CAPA 000907
  - CAPA 000913

- The creation, review, and sign-off of the FPIRs may take up to four months or more to complete. No documentation of this process is attached to the CAPA file until the FPIR has the final review and signatures.
  - CAPA 000644 and CAPA 000783 (000818) do have completed FPIRs attached to them, but the completion dates of these FPIRs were 11 months or more after the initial CAPA was opened.

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Annotation: Promised to correct by 4/30/08.

Reference: 21 CFR 820.100(a)(2)

Supporting Evidence:
Exhibit #78 – Corrective and Preventive Action, GP.1401, Version 3.0, 12/29/04
Exhibit #79 – Corrective and Preventive Action, GP.1401, Version 4.0, 9/27/06
Exhibit #80 – Corrective and Preventive Action, GP.1401, Version 5.0, 4/9/07
Exhibit #23 – Corrective and Preventive Action, GP.1401, Version 6.0, 9/28/07
Exhibit #81 – Field Product Impact Assessment, RCC.1401.0002, Version 3.0, 10/30/04
Exhibit #82 – Field Product Impact Assessment, RCC.1401.0002, Version 4.0, 9/21/06
Exhibit #24 – Field Product Impact Assessment, CRM.1401.0002, Version 1.0, 10/5/07
Exhibit #83 – Field Corrective Action, 1401.P, Version D, 10/24/03
Exhibit #84 – 000834: CAPA Reports
Exhibit #85 – 000842: CAPA Reports
Exhibit #86 – 000876: CAPA Reports
Exhibit #87 – 000888: CAPA Reports
Exhibit #88 – 000907: CAPA Reports
Exhibit #89 – 000913: CAPA Reports
Exhibit #90 – 000783: CAPA Reports
Exhibit #91 – 000818: CAPA Reports
Exhibit #43 – 000644: CAPA Reports

Discussion with Management:
During the review of the CAPA files it was noted that in several files had intervals of longer than four months for the time from the initiation of the CAPA to the completion of the first revision of the FPIR. The FPIR is used when a CAPA has been started for a problem noted in the field and there is affected product in the field. See **Exhibit #24** for the most recent revision of the FPIR process. The review conducted includes a health hazard analysis and what action is to be taken, including field actions.

We discussed that if this was their process for risk assessment and determination of whether a field action was warranted, it should be conducted early in the process. Mr. Holgers stated that the FPIR did not take that long to complete and was in draft from for the majority of the time. But that upper management needed to review and approve the document and many times they required revision prior to signing off on it. This could add two or more months to the process. When we asked to see

some "in process" FPIRs, we were told that they were in draft form and thus they were not able to let us view them. I noted that without seeing a document we would have to presume that they were not created.

We also discussed that during the FPIR process there was a section for likelihood of occurrence. During our review it was relayed to us that when the firm determines this rate they felt that the root cause was needed and that this determination of root cause could add time to the completion of the FPIR. I then explained that to conduct a recall it is not necessary to have the root cause of the issue determined. With that in mind this should not be a factor in their process for determining the need for a recall.

Table 1 below shows the CAPA files that did not have FPIRs completed. Table 2 is for the three CAPAs that had completed FPIRs in the files.

TABLE 1

CAPA #	Initiation Date of CAPA	FPIR Task Assigned	Due Date for FPIR Completion	Number of Months without FPIR①	Number of Months to FPIR Due Date
000913	8/31/07	10/30/07	2/28/09	4 months	6 months
000842	1/25/07	2/23/07	12/14/07	12 months	12 months
000876	5/10/07	5/14/07	12/18/07	7 months	7 months
000834	12/21/06	1/4/07	1/31/08	12 months	13 months
000888	6/12/07	Not assigned	Not assigned	6 months	--
000907	8/15/07	10/18/07	12/21/07	4 months	4 months

①At the completion of this inspection no FPIRs were in these CAPA files. The calculation of time in months was from the initiation of the CAPA to the last date of the inspection.

TABLE 2

CAPA #	Initiation Date of CAPA	FPIR Task Assigned	FPIR Completion	Number of Months without FPIR
000783②	8/7/06	10/2/06	7/20/07	11 months
000818②	11/3/06	10/2/06	7/20/07	8 months
000644	7/27/05	10/31/06	4/9/07	21 months

②These two CAPAs were linked together. The FPIR for CAPA 000783 was used for CAPA 000818 as well.

GENERAL DISCUSSION WITH MANAGEMENT

The closing meeting was attended by Mr. Holgers, Ms. Rottunda, Mr. Gates, Ms. Fuher, and Mr. Mangipudi. I issued the one-item FDA-483 to Ms. Rottunda and we discussed the item. Management promised to correct the item; the annotation is listed with the observations above.

Four verbal comments/observations were made to management, first now that you have used the CARELINK data for CAPA investigation and in a field action decision the expectation has been set that it will be used for similar issues, second was a reminder that recalls are required whenever adulterated or misbranded product is in the field and that a root cause is not needed before the recall is initiated, third was that the (b) (4) process should be proceduralized in the CAPA process to ensure that data coming from these meetings are collected in the CAPA file, and lastly the firm should review their sterilization validations and assure that it is clear that their Process Control Device is harder to sterilized than the validated product. Management stated that they would review these processes and assure that they would make the necessary changes.

ADDITIONAL INFORMATION

Below are responses to questions posed by CDRH about the inspection at Medtronic CRDM. Answers to questions are italicized. The final item is two discussion items are a follow-up to a memo received from the recent Galway, Ireland inspection and a follow-up to a Consumer complaint received by the district.

Email Dated 10/17/07

- Components
  - Which, if any components for the Sprint Fidelis Leads come from foreign countries? Which countries do they come from?

Answer: (b) (4) .

- MDRs
  - Information related to how they determined that 5 of 15 deaths were likely/possibly related to lead fracture, and how they determined 10 were not.

Answer: The firm's Medical Director Dr. David Steinhaus, reviewed all the complaints along with strip charts and ECGs. In his medical opinion only four deaths were likely related to the device and one death was possibly related to the device. The others were reported via MDR to be on the conservative side, even though the Medical Director did not believe the device caused the death. (b) (6)

  - Explanation for statements of "No anomalies found" for MDRs (including death – Firm control number E691064) that Medtronic has determined are likely or possibly related to the lead fracture. We think that the fracture should qualify as an anomaly.

Answer: The statement of no anomalies found have to do with the testing of the device. In E691064 the ICD was tested along with the lead. It was noted that the ICD did not have any anomalies found in this bench testing. On all complaints this statement is only used when bench testing is completed on the returned lead or ICD and the bench testing all passes.

- 10 voluntary Medwatch reports (see attachment for list) which do not appear to match up with MDRs reported by Medtronic…why were these not reported by the company?

Answer: These reports were submitted with the November batch of MDRs..

- Design controls and analyses of/trending of the failures
  - How were they feeding the information about failures increasing back into the design control loop to see where improvements are needed? Was that being tracked in PR and fed to MN?

Answer: Trend and complaint data are tracked in both MN and PR. This data if increasing or an unexpected anomaly happens will trigger a CAPA. The CAPA system is a global system so both sites have access to it and both sites are usually involved with CAPAs. The CAPA system is the trigger for a FPIR which will recommend a fix to the failure or if an action is to be taken. In this process if changes are to be made an ECO is started which then loops into the design change control process. PR only tracks in process failures whereas MN tracks returned product and complaint failures.

  - When were atypical device analyses undertaken? When did the projected 5 year survival rates become alarming?
    - Combination of data from RPA, SLS & CareLink transmissions
    - Analyses by age groups

Answer: Device analysis was started with CAPA 644 on 7/27/05. (b) (4) .
Analysis of failures by age group was conducted in August and October 2007. These are attached as **Exhibits #75-77**. *The firm states that the age analysis data showed that the Fidelis leads were performing as other leads, when it came to age. This did not teach them anything new.*

  - Details regarding the new bench test methods involving (b) (4) that Medtronic described in the meeting
    - protocols, results
    - How did they set pass/fail criteria

Answer: This test was in process of being validated when the recall started. At that time all validations and design projects for Fidelis were put on hold. So this test is still waiting to be validated and has not been used in production of any other lead.

- Disposition of returned/not yet distributed devices

- What are they doing with the devices that were just made over the weekend/Monday morning (since they only halted production with the announcement on Monday)? We presume they will be treating the devices they have not yet distributed as they would returned product…will they be destroying them?

Answer: All devices have been put "on hold". Those devices in the field will be returned to Medtronic. Devices will be (b) (4) *. No leads will be reworked or ever sold again.*

- Reporting to FDA
  - Insight/documentation as to how/when they decide not to submit a manufacturing or design change as a 30-day notice or PMA supplement (either 180 day or real time) and when the changes don't get submitted as any of the above and also aren't included in the annual report. Medtronic's criteria for making these decisions appear to differ greatly from some of their competitors and also from FDA interpretation of the regs.
    - In particular, how have they documented all design and manufacturing changes for the Sprint Fidelis Leads since approval under P920015/S29 & S30?

Answer: All major design changes are submitted per their procedure to FDA for review in PMA supplements. Sine Supplements S29 and S30 no major changes have been made, any changes made were updated in their Annual Reports. ECOs for Fidelis are listed in the following logs, **Exhibits #92 & 93**.

- Was the design change approved on 7/3/07 under P920015/S37 implemented into production?

Answer: Yes this design change was implemented on 6/4/07.

Email dated 10/24/07

1) Medtronic used a (b) (4) on the Sprint Fidelis than it had on earlier leads. Did the company inform the agency of the change? Why was the change made?

Answer: The change was made during the design of the Fidelis. (b) (4) *was changed from* (b) (4) *This change was submitted with the PMA application. See* **Exhibits #94 & 95** *for the process qualification and characterization study for this change.*

Email dated 10/25/07

Follow up to MDR# 2649622-2007-01986, Device SN: LFJ15884V Model 6949.

Answer: The firm did request information from the sales representative about this device. He stated that he never received the device from the physician. The hospital was then called about the

location of the device. The hospital stated that the device was given to their risk management and was not returned to the manufacturer.

Email dated 11/8/07

What algorithms are used with the Fidelis? Why did the device not detect the inappropriate shocks?

Answer: There are several answers to this question. First the algorithms for the ICD model are based on (b) (4) . *See* **Exhibit #96** *for some PowerPoint slices explaining this. Second the ICDs do contain programming in them to alarm when high impedance is sensed. But many doctors do not turn on these alarms and thus the patients are not alerted of the high impedance problem. Third is that if the fracture is only causing intermittent sensing, the ICD may not notice that there is a problem because the readings are in the correct range most of the time. This is because for most of the time the coil is still touching and thus working. But when the fracture comes apart for a brief period no sensing is happening. If there is no sensing there is no ability to shock the patient. Finally the physicians have the ability to set the impedance ranges based on patient physiology, in this case if they set the range incorrect inappropriate shocks may happen because of the wrong settings.*

Memorandum dated 11/8/07

Major Questions:

1. The sponsor has provided a summary report *CAPA #00644: Cable Fractures in* (b) (4) . This report provided a failure analysis of one of the four primary fracture locations occurring in the Fidelis leads. However, to thoroughly understand the specific cause of failures in all locations (b) (4)), complete failure analysis should be provided for the remaining three locations. Included in these reports, we would like photomicrographs displaying fracture surfaces with specifics regarding the predominant failure mode(s).

ANSWER: Attached are Summary Reports for failure modes I, II, and III **Exhibits #49-50, 47.** *Three separate TIMS (Technical Information Memo) for failure mode IV* (b) (4) *)* **Exhibits #59-61.**

2. There are three major manufacturers of ICD leads in the United States. It appears that each manufacturer may use unique testing protocols for mechanical bench testing. A detailed description of all mechanical testing protocols that have been performed by each manufacturer would significantly aid our ability to recommend new and improved testing protocols. Please provide us with all mechanical testing protocols identifying the lead component tested as well as the acceptance criteria. *This question was not answered.*

3. In order to develop bench tests that appropriately simulate physiologic conditions, the expected loading modes (tension/compression, bending, torsion, etc.) on the lead should be well understood. Please describe the expected loading modes on the lead during normal use.

ANSWER: The bench testing had a design assurance test completed for it. I also am attaching a list of all the in-process tests that are completed on the leads in Puerto Rico (**Exhibit #97**). **Exhibit # 98** *is a copy of the summary of all the bench tests that were completed on the Fidelis Models.*

Minor Questions:

4. Sponsor stated that location IV fractures occurred (b) (4) . Since the (b) (4) , it is important to understand where these fractures occurred. Did the fractures occur on (b) (4) ? In addition, does (b) (4) ?

ANSWER: The Final Technical Communication TIM answers this question (**Exhibit #61**).

5. It is known that small radius of curvatures produce kinking. Does the sponsor provide a critical radius of curvature that results in damage of leads?

ANSWER: No they do not have a critical radius of curvature known to damage the leads. They stated that they test to known standards, (b) (4) .

6. Identification of the maximum stress locations is important to determining failure of lead. This is especially critical in a composite device such as these leads. Has finite element analyses been performed to determine the location of stress concentrations in this composite structure? A factor of safety analysis from the FEA would aid in understanding the safety for the leads to yield/fracture.

ANSWER: No. They explained that an FEA (b) (4)

7. We are concerned that (b) (4) . Please provide a comparison table of the (b) (4) for both the Fidelis and the Quattro leads.

ANSWER: A spreadsheet was supplied that compares Defibrillation leads. See **Exhibit #99**.

8. Since we do not know where the failures occurred, there is a possibility that these failures occurred at (b) (4) . Please specify the connections between (b) (4) (Are they welded, crimped, or bonded).

ANSWER: The answer for this is supplied in (b) (4) *Summaries* **(Exhibits #49-50, 47)**.

9. Do the Fidelis cables use the same material as the Quattro?

ANSWER: (b) (4) .

10. Since we do not have a comprehensive list of the failures that occurred, please let us know if many of the fractures occurred in a specific cable/coil (i.e. pacing coil, cable for RV, cable for SVC, or sensing cable). Also, within a cable, are fractures occurring in wires at the surface or at the center of the bundle?

ANSWER: This information is located in the Summary Reports and TIMs. But as a quick answer for (b) (4) . *Refer to* **Exhibits #49-50, 47, 59-61**.

Email dated 11/14/07

Since the approval of the Sprint family leads, provide the numbers of leads implanted in the US by model number (10 different), for each calendar year.

Answer: This is attached as **Exhibit #100**.

Email dated 11/15/07

Why were these MDRs submitted late? (Mfr Report No: 2649622-2007-02463 & Mfr Report No: 2649622-2007-03070)

Answer: The Complaint Database was being reviewed for a non Fidelis related reason. During this the reviewer, who was not the original Complaint Reviewer, noted these two complaints. A full review of the complaints was made during a meeting of the complaint department and it was decided that the initial decision not to report these event was incorrect. At that time the two reports were submitted to the FDA.

October 2007 FDA presentation reference to Physician Quality Council

In the October 2007 presentation you gave to FDA you referenced a Physician Quality Council, when did this take place.

Answer: It was held March 8-9, 2007. See ***Exhibit #101*** *for more information.*

Follow-up to Guide Catheter question from Galway Inspection

We received a request to follow-up with a question raised in the most recent Galway, Ireland inspection as to why the firm did not conduct a recall for Guide Catheters that had been distributed that were possibly mislabeled. I asked the firm what they were doing with the possibility of six

mislabeled packages that were left in the field. Mr. Holgers stated that per their FPIR **(Exhibit #102**) completed in November 17, 2006, the predicted number of critical injuries was 0, and so complaints were being watched for more failures. To date no other complaints for this issue have been seen. He stated that there was a prediction of a possible six units in the field but all previous complainants noticed the mislabel prior to use and it was expected that any new physicians finding this problem would also notice it before use, thus there was no risk to the patient. Also the shelf life of this product is short due to the amount used in surgeries so it was thought that all six possible mislabeled units would be used or discarded by now.

Follow-up to Consumer Complaint #40468

The district received a consumer complaint about a Medtronic ICD that was thought to have been malfunctioning and repeatedly giving inappropriate shocks to a patient, who subsequently passed away. I asked the firm if they had any information on the serial number reported in the complaint. They provided me with the complaint file, #E681356 (**Exhibit #103**). This event had been reported to the firm and the device was returned. No destructive testing was conducted on the device as requested by the complainant. The event files from the ICD were downloaded and reviewed. This review showed that the patient was in Ventricular Fibrillation/Ventricular Tachycardia at the time the device was shocking repeatedly. Thus the device was acting as it was programmed to do. Also the patient's physician was spoken to by the firm and he stated that the death was not related to this device.

Article supplied by the firm on small diameter high-voltage leads

The firm supplied us with the following articles that they believed are pertinent to their decisions when to recall Fidelis. **Exhibit # 104** is the article written by Dr. Hauser. **Exhibits #105 & 106** are article written by other physicians that do not necessarily agree with Dr. Hauser.

EXHIBITS COLLECTED

#1 – Cardiac Rhythm Disease Management Staff, 8/24/07
#2 – Quality & Regulatory Staff, 10/29/07
#3 – Attain StarFix 4195, M924275A001, Rev. A,
#4 – Medtronic Sprint Fidelis Family of ICD Leads, UC200403562a EN, 2004
#5 – Business and Quality Management Manual, Version 8.0, 8/31/07
#6 – Therapy Delivery Systems Product Development Guidance Product Overview, THD.0401.0007, Version 2.0, 10-April-07
#7 – Project Charter: Attain Secure OTW Model 4195 (formerly: Reversible Fixation), B4435
#8 – CRM Therapy Delivery Division Design Input Review Report - Attain Secure OTW Model 4195, 12/19/2002, BL0005775
#9 – Product Standard - Leads, Silicone and Polyurethane, 218021, Rev. D, 10/28/96

#10 – Product Spec - Lead, Cardiac Vein, Unipolar, Curved, Over-The-Wire, Deployable Lobes, 86313, Rev. J
#11 – Drawing - Lead Assy - Cardiac Vein, Unipolar. Over the Wire, Deployable Lobes, 502992, Size D, 12/3/01
#12 – Lead Model 4195 Packaging and Design Verification, and Rice Creek Facility Qualification Test Plan, NW030724.001, 12/11/03
#13 – Lead Model 4195 Packaging and Design Verification, and Rice Creek Facility Qualification Test Report, NW040107.001, 2/26/04
#14 – Model 4195 In Vitro Bench Test Regulatory Summary Report, BL0007634, Version 6.0, 12/18/06
#15 – Lead Model 4195 Design Validation Report, 10/7/2005, BL0009781
#16 – CRM Therapy Delivery Division Design Review Report, BL0007582, 2/13/04
#17 – FMEA, for Lead Model 4195, BL0005719, 12/15/06
#18 – Memo - Sterilization Strategy for Medtronic Model 4195 Lead, 1/3/03
#19 – Sterilization Qualification Protocol for the Medtronic Model 4195 Over-The-Wire (OTW) Lead Sterilized and Aerated in the (b) (4)
#20 – Sterilization Qualification Report for the Medtronic Model 4195 Over-The-Wire (OTW) Lead Sterilized and Aerated in the (b) (4)
#21 – Initial Complaint Review, CSS.2104.0001, Version 2.1, 18-Jan-07
#22 – MDR Review, CSS.2105.0001, Version 5.0, 23-Jul-07
#23 – Corrective and Preventive Action, GP.1401, Version 6.0, 18-Sep-07
#24 – Field Product Impact Assessment, CRM.1401.0002, Version 1.0, 5-Oct-07
#25 – Corporate - Field Corrective Action Policy, CQRA-004, Revision A, 5-Sep-01
#26 – Fidelis Field Communication Plan, Final, 10-Oct-07
#27 – MDR with Complaint Summary E716070, 2649622000200700363, 3/23/2007
#28 – MDR with Complaint Summary E691064, 6000094000200600606, 9/15/2006
#29 – MDR with Complaint Summary E705409, 2649622000200700606, 1/22/2007
#30 – MDR with Complaint Summary E736594, 6000094000200700444, 9/28/2007
#31 – MDR with Complaint Summary E734526, 2649622000200702437, 9/11/2007
#32 – MDR with Complaint Summary E665003, 2649622000200600458, 2/23/2006
#33 – MDR with Complaint Summary E714541, 2649622000200701102, 5/3/2007
#34 – MDR with Complaint Summary E710398, 2649622000200700795, 2/21/2007
#35 – MDR with Complaint Summary E628216, 2649622000200701351, 6/25/2007
#36 – MDR with Complaint Summary E617763, 2649622000200500461, 3/29/2005
#37 – MDR with Complaint Summary E688231, 2649622000200601344, 8/27/2006
#38 – MDR with Complaint Summary E664758, 2649622000200600546, 3/2/2006
#39 – MDR with Complaint Summary E690208, 6000144000200600193, 9/6/2006
#40 – MDR with Complaint Summary E706113, 2649622000200700631, 2/12/2007
#41 – MDR with Complaint Summary E635791, 2649622000200600003, 11/11/2005
#42 – CD which contains a Complaint Log for all Fidelis Complaints up to 10-25-2007
#43 – 000644: CAPA Reports, #644, 7/27/2005

#44 – (b) (4) - Fidelis CAPA Team Meeting Minutes, Dec 05 - May 06
#45 – Fidelis CAPA File: Process Change and Variance Review of Fidelis Models, 8-Feb-06
#46 – Fidelis CAPA File: Process Change Review of Fidelis Models, 20-Feb-06
#47 – Summary Report - CAPA #000644: Cable Fractures at the (b) (4)
#48 – Fidelis CAPA File: Process Change Review of Fidelis Models, 23-Feb-06
#49 – Summary Report - CAPA #00644: Cable Fractures in the (b) (4)
#50 – Summary Report - CAPA #00644: Cable Fractures in the (b) (4)
#51 – CRDM Technical Services U.S. Tech Note - TTN06-101 Preventing Fractures in (b) (4)
#52 – Fidelis CAPA Team Project Review - Peer Review, 5-May-06
#53 – Interoffice Memo - Fidelis Fracture Statistical Analysis as of 1 Aug 2006, Revision B, 25-Oct-06
#54 – Inter-Office Memo Rationale for FPIR, 6/1/06
#55 – 000854: CAPA Reports, 854, 3/15/2007
#56 – Summary of Meeting Minutes, 16-Oct-06
#57 – Meeting Notes From Dr. Rigden, 26-Jan-07
#58 – Summary of 1-11-07 U of MN Cadaver Study
#59 – Baseline Activities
#60 – (b) (4) TIM#3 Agenda, 7/11/07
#61 – Fidelis (b) (4) Team Final Technical Communication
#62 – Field Product Impact Reports Fidelis Cable and Fractures CAPA Number: 000644 & 000845 Version A, BL0016542, Version 2.0, 4/9/2007
#63 – Field Product Impact Reports Fidelis Cable and Fractures CAPA Number: 000644 & 000845 (version B), BL0016542, Version 3.0, 4/10/2007
#64 – Field Product Impact Report Fidelis Cable and Coil Fractures, 000644 & 000854, Version C, 10/10/2007
#65 – Field Product Impact Report Fidelis Cable and Coil Fractures, 000644 & 000854, Version D, 10/17/2007
#66 – Email from Dave Schaenzer 6949 data for reggie.xls, 13-Mar-07
#67 – Project Name: (b) (4) , Revision A, 8-Oct-07
#68 – 1-Jun-07 Lead & Accessory Product Performance Teleconference Meeting Minutes and PowerPoint Presentation, 18-Jun-07
#69 – 27-Aug-07 Lead & Accessory Product Performance Teleconference Meeting Minutes and PowerPoint Presentation, 27-Aug-07
#70 – Tech Note - (b) (4) - 101, 14-Mar-07
#71 – Interoffice Memo - CAPA 000644 Timeline, 15-Mar-07
#72 – Summary Report - CAPA #00644: Cable Fractures in (b) (4) , 20-Mar-07
#73 – Design Evaluation Test Report for (b) (4)

#74 – Memo to CAPA000644 File - DF1 Tech Note Effectivity Check, 24-May-07
#75 – Analysis of Fractures per Model Family by Patient Age at Time of Implant
#76 – Analysis of Model 6949 Fractures Based on DRS/RPA and CareLink & DRS/RPA Datasets
#77 – Analysis of Model 6949 Fractures by Patient Age at Time of Implant
#78 – Corrective and Preventive Action, GP.1401, Version 3.0, 29-Dec-04
#79 – Corrective and Preventive Action, 10/27/2006, Version 4.0, GP.1401
#80 – Corrective and Preventive Action, 4/9/2007, Version 5.0, GP.1401
#81 – Field Product Impact Assessment, RCC.1401.0002, Version 3.0, 30-Oct-04
#82 – Field Product Impact Assessment, RCC.1401.0002, Version 5.0, 21-Sep-06
#83 – CRDM - Field Corrective Action, 1401.P, Version D, 24-Oct-03
#84 – 000834: CAPA Reports, 12/21/06
#85 – 000842: CAPA Reports, 1/25/07
#86 – 000876: CAPA Reports, 5/10/07
#87 – 000888: CAPA Reports, 6/12/07
#88 – 000907: CAPA Reports, 8/15/07
#89 – 000913: CAPA Reports, 8/13/07
#90 – 000783: CAPA Reports, 8/7/06
#91 – 000818: CAPA Reports, 11/3/06
#92 – Fidelis ECOs List, 24-Oct-07
#93 – Fidelis 500 level ECOs
#94 – Characterization Study Report - (b) (4)
#95 – Process Qualification Report - (b) (4)
#96 – (b) (4) Pacing Imp. (PowerPoint)
#97 – Mechanical Testing Performed in PR
#98 – 6949/6931 Bench Test Summary, MP031028.001, 3-Nov-03
#99 – Updated Medtronic Defibrillation Leads Comparison, 15-Feb-07
#100 – Annual Sales for Sprint Family of Leads
#101 – Email from Tim Samsel about Physician Quality Councils, 14-Nov-07
#102 – Field Product Impact Report - Attain 6216A-MP Multi-purpose Guide Catheter for Left Heart Delivery, 11/17/06
#103 – Complaint Summary, E681356
#104 – Early Failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead, doi:10.1016/j.hrthm.2007.03.041, Robert G. Hauser, MD
#105 – Small-diameter defibrillation electrodes: Can they take a licking and keep hearts ticking?, doi:10.1016/j.hrthm.2007.05.001, Charles D. Swerdlow, MD
#106 – Lead failures: Dealing with even less perfect, doi:10.1016/j.hrthm.2007.05.002, Bruce L. Wilkoff, MD

ATTACHMENTS

- Form FDA 482, Notice of Inspection
- Form FDA 483, Inspectional Observations (Modified)
- Form FDA 483, Inspectional Observations (Original)
- Copy of HFZ-306 assignment dated October 17, 2007, FACTS Assignment #891086 (with CD)

Billi Jo M. Johnson

Billi Jo M. Johnson, Investigator

Janis R. Armendariz, Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
212 3rd Ave. South Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134	10/18/2007 - 12/21/2007*
	FEI NUMBER 2182208

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Sara M. Rottunda, Director, Quality Systems & Compliance

FIRM NAME	STREET ADDRESS
Medtronic Inc. Cardiac Rhythm Managment	8200 Coral Sea Street NE
CITY, STATE, ZIP CODE, COUNTRY Mounds View, MN 55112	TYPE ESTABLISHMENT INSPECTED Medical Device

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The corrective and preventive action procedures addressing the investigation of the cause of nonconformities relating to product, processes, and the quality system were not implemented.

Specifically, CAPA procedure GP.1401, various revisions from 2006 to present, requires a FPIR to be completed during the investigate stage of the CAPA process, when a risk assessment is needed. The FPIR procedure RCC.1401.0002, various revisions from 2006 to present, states that the FPIR or Field Product Impact Report, is completed when a CAPA request has the potential to affect clinical or market-released product.

- The following CAPAs, which affect clinical or market-released product, do not include further documentation of the FPIR process:
  - CAPA 000834
  - CAPA 000842
  - CAPA 000876
  - CAPA 000888
  - CAPA 000907
  - CAPA 000913

- The creation, review, and sign-off of the FPIRs may take up to four months or more to complete. No documentation of this process is attached to the CAPA file until the FPIR has the final review and signatures.
  - CAPA 000644 and CAPA 000783 (000818) do have completed FPIRs attached to them, but the completion dates of these FPIRs were 11 months or more after the initial CAPA was opened.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mounds View, MN 55112	Medical Device

Observation Annotations

Observation 1: Promised to correct by 4/30/2008.

JRQ

SEE REVERSE OF THIS PAGE	This is a modified document. JRQ 12/21/07 BMJ	DATE ISSUED 12/21/2007

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
212 3rd Ave. South Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134	10/18/2007 - 12/21/2007*
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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mounds View, MN 55112	Medical Device

*** DATES OF INSPECTION:**
10/18/2007(Thu), 10/19/2007(Fri), 10/23/2007(Tue), 10/24/2007(Wed), 10/25/2007(Thu), 10/26/2007(Fri), 10/29/2007(Mon), 11/05/2007(Mon), 11/06/2007(Tue), 11/07/2007(Wed), 11/09/2007(Fri), 11/14/2007(Wed), 11/15/2007(Thu), 11/19/2007(Mon), 11/20/2007(Tue), 11/26/2007(Mon), 11/27/2007(Tue), 11/28/2007(Wed), 11/29/2007(Thu), 12/03/2007(Mon), 12/10/2007(Mon), 12/11/2007(Tue), 12/13/2007(Thu), 12/14/2007(Fri), 12/17/2007(Mon), 12/18/2007(Tue), 12/21/2007(Fri)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Billi Jo M. Johnson

Billi Jo M. Johnson, Investigator

Janis R. Armendariz, Investigator 12/21/07

JRA

SEE REVERSE OF THIS PAGE	This is a modified document. 12/21/07 JRA	DATE ISSUED 12/21/2007