USER: **WEEKS, SUSAN M (smw)**

FOLDER: **P920015 - 24 pages (Subset of Folder)**

COMPANY: **MEDTRONIC INC. (MEDTRONIC)**

PRODUCT: **DEFIBRILLATOR, AUTOMATIC IMPLANTABLE CARDIOVERTER (LWS)**

SUMMARY: **Trade Name: MEDTRONIC(R) TRANSVENE LEAD SYSTEM**

DATE REQUESTED: **Mon Nov 03 18:48:08 2008**

DATE PRINTED: **Mon Nov 03 18:49:13 2008**

PRINTER: **file**

Table of Contents

CORRESPONDENCE - 5 pages **1**

SUPPLEMENT - 17 pages **6**

MEMORANDUM

DATE: SEP 10 2001

TO: The Record

FROM: Kent A. Berthold, Consumer Safety Officer
Cardiovascular and Neurological Devices Branch, DOE III, OC, CDRH
Thru: Christy Foreman, Acting Deputy Director, DOE III CLF 9/10/01

RE: P830061/S032, P850089/S047, P890003/S064, P900061/S045, P920015/S023, P930039/S010, P950024/S004, P980016/S019, and P980050/S007
Medtronic Pacing Leads
Received: July 17, 2001

FIRM: Cardiac Rhythm Management
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, Minnesota 55432

On July 17, 2001, we received a 30-Day Notice from Cardiac Rhythm Management, Medtronic, Inc. regarding a change in the supplier of (b)(4) (b)(4)

COMPLIANCE REVIEW

Our review determined that the applicant had submitted adequate data to demonstrate that the change in the manufacturing process was conducted in accordance with the Quality System Regulation.

ODE REVIEW

The ODE review determined that the firm submitted sufficient information to address safety and effectiveness issues for the change in the manufacturing process. A copy of ODE's review is attached.

CONCLUSION

As a result of the review of the 30-Day Notice by OC/ODE, it was decided that a 135-Day Supplement is not required. A copy of the

25

letter sent to the sponsor is attached.

Kent A. Berthold

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Attachments:
ODE's review
Letter sent to sponsor

Prep:KABerthold:8-30-01
Reviewed:CForeman:
Final:kab:

Original:
30-Day Notice File

bcc:
HFZ-306 (Comella)
HFZ-340 (Foreman, 3)
HFZ-341 (Berthold, Firm File)
HFZ-402 (Nguyen, Wolanski)
HFZ-450 (Donelson)

Tracking
C:\MY DOCUMENTS\LETTER\30-DAY NOTICE, REVIEW MEMORANDUM, MEDTRONIC

Berthold, Kent A.

From: Donelson, Jan
Sent: Tuesday, August 07, 2001 5:14 PM
To: Foreman, Christy; Berthold, Kent A.
Subject: P830061/S032, P850089/S047, P890003/S064, P900061/S045, P920015/S023, P930039/S010, P950024/S004, P980016/S019, and P980050/S007

Christy and Kent -

Re: P830061/S032, P850089/S047, P890003/S064, P900061/S045, P920015/S023, P930039/S010, P950024/S004, P980016/S019, and P980050/S007
Medtronic Pacing Leads
Received: July 17, 2001

DCRD has reviewed the above document, as well as your draft letter to the applicant regarding this 30-Day Notice requested an evaluation of the change in the supplier of (b)(4) We have no unresolved concerns regarding safety and effectiveness issues.

In addition, we find your letter acceptable for issuance with modification as tracked in the letter on the L drive.

If you have any questions, please contact me at (b)(4)

(b)(4)

(b)(4)

28

DEPARTMENT OF HEALTH & HUMA.. SERVICES

Pu.. Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 2001

Kristy K. Mollner, RAC
Product Regulation Manager
Cardiac Rhythm Management
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432

Re: P830061/S032, P850089/S047, P890003/S064, P900061/S045, P920015/S023, P930039/S010, P950024/S004, P980016/S019, and P980050/S007
Medtronic Pacing Leads
Received: July 17, 2001

Dear Ms. Mollner:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has evaluated your premarket approval application (PMA) 30-day Notice. The 30-day Notice requested an evaluation of the change in the supplier of (b)(4) (b)(4)

Based on the information submitted, FDA has determined that submission of a 135-day PMA supplement is not required.

If you have questions concerning the letter, please contact the Field Programs Branch at (301) 594-4695 or the PMA Staff at (301) 594-2186.

Sincerely yours,

Thinh Nguyen
Director, Premarket Approval
Application Program
Program Operations Staff
Office of Device Evaluation
Center for Devices and
Radiological Health

P920015/S25/Cr

For complete submission information, please refer to P900061/S51; copy 2

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 06, 2001

STACEY PAETSCHOW WESSMAN
MEDTRONIC, INC.
RICE CREEK CENTER
7000 CENTRAL AVE. N.E.
MINNEAPOLIS, MN 55432

Dear MS. PAETSCHOW WESSMAN:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your PMA SUPPLEMENT. This PMA SUPPLEMENT has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

PMA Number: P920015/S025
Dated: 31-OCT-2001
Received: 05-NOV-2001
Device: TRANSVENE/SPRINT SUBCUTANEOUS LEAD

Any questions concerning this submission should be directed to the undersigned at (301)594-1184. All future correspondence regarding this PMA should be identified with the PMA number assigned above and should be submitted with the required number of copies to:

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

Sincerely yours,

-A-

Janet L. Donelson
Assistant Director for Program Operations
Division of Cardiovascular and
Respiratory Devices

Office of Device Evaluation
Center for Devices and
Radiological Health

Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432.3576 USA
www.medtronic.com

tel 763.514.4000

31 October 2001

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

SP'10

Re: MEDTRONIC/VITATRON SPECIAL PMA SUPPLEMENTS –CHANGES BEING EFFECTED TO PMA P920015/SX

This Special PMA Supplement –Changes Being Effected applies to PMA P920015. The applicable submission numbers also affected by this change are as follows:

P900061 (Master Submission)	**P920015**
P970012	**P850089**
P980016	**P930039**
P980035	**P950024**
P980050	**P830061**
P990001	**P790018**
P010015	

Medtronic Cardiac Rhythm Management is submitting in triplicate this Special PMA Supplement – Changes Being Effected for the above referenced PMAs. As a result of a 483 received by the Medtronic Heart Valve division, a manufacturing change will be implemented that enhances the monitoring of (b)(4) (b)(4) during the sterilization process. Each of the devices referred to in the PMAs listed above, is sterilized using the same sterilization method. The addition of the (b)(4) (b)(4) sensor **does not represent a change in the sterilization process**, but an additional monitoring technique.

Based on the recommendation of Mr. Thinh Nguyen, ODE, a **"Master Submission"** supplement that contains all the information required of a Special PMA supplement is being provided to the following FDA divisions: Division of Cardiovascular and Respiratory Devices, the Division of Dental, Infection Control, and General Hospital Devices, Division of General, Restorative and Neurological Devices and Division of Reproductive, Abdominal, and Radiological Devices. For the remaining affected supplements within the same division, Special PMAs, each containing only the Master Submission cover letter and referring to the information in the **"Master Submission,"** are being submitted.

Medtronic Cardiac Rhythm Management has provided a **"Master Submission"** dated 31 October 2001, under separate cover. This **"Master Submission"** contains a detailed description of the Special PMA Supplement –Changes Effected to PMA number **P900061/SX**. A list of the device model numbers affected by this change is provided in Table 1. Current and future products approved under this PMA will utilize this (b)(4) (b)(4) sensor.

Table 1. Currently Marketed Devices Affected by this Change

Product Family	Model Number/Vitatron Name	PMA Number
Leads/Accessories*		
Transvene lead	6937	P920015
Sprint	6932	P920015
Sprint	6942	P920015
Sprint	6943	P920015
Sprint	6945	P920015
Sprint	Sprint Quattro 6944	P920015
Sprint	Sprint Quattro Secure 6947	P920015
Subcutaneous Lead	6996	P920015

*It should be noted that one or more model numbers may be included in these previously approved product families.

This submission includes confidential commercial and trade secret information, and we request that it be given the maximum, protection allowable by law.

If additional information is required, please contact the undersigned.

Kind Regards,
MEDTRONIC, INC.

Stacey Paetschow Wessman
Product Regulation Manager
Cardiac Rhythm Management
Tel: 763.514.2965
Fax: 763.514.6424

[redacted]
P920015/S27. C1

For complete submission information please refer to P830061/ S36; copy 1

P920015/S27; C1

[redacted]

Medtronic

Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576
www.medtronic.com

tel 763.514.4000

March 3, 2003

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
ATTN: 30-day Notice
9200 Corporate Blvd.
Rockville, Maryland 20850

CC: Food and Drug Administration
Office of Compliance
Field Programs Branch (HFZ-306)
ATTN: 30-day Notice
2098 Gaither Road
Rockville, Maryland 20850

FDA/CDRH
2003 MAR -4 A 11:45
RECEIVED

RE: 30-DAY NOTICE PMA Supplement to the following:
P830061
P850059
P920015
P930039
P980016

Dear Sir or Madam:

Pursuant to 21 CFR 814.39, this 30-Day PMA Supplement is being submitted in triplicate (One copy provided to the Office of Compliance and 2 copies provided to the Office of Device Evaluation). This PMA supplement is being submitted to notify FDA of a change in supplier of raw material or components. Medtronic has chosen (b)(4) as an alternate supplier of (b)(4) markets (b)(4) under the trade name (b)(4) Currently (b)(4) supplies (b)(4) under the trade name, (b)(4)

1. Description of Change
This change provides an alternate supplier to (b)(4) material. The alternate supplier, (b)(4) will market the (b)(4) under the trade name (b)(4)

This change affects all leads that currently contain the (b)(4) material. This supplier change will be implemented in the market released leads outlined in the following table. Additionally, the qualification contained within this 30-day notice for the supplier change of (b)(4) will apply to leads that will implement the supplier change at a later date.

In addition, there were no labeling changes as a result of this supplier change.

Currently Marketed Leads Affected by Supplier Change of (b)(4) (b)(4)

Medtronic Family	Medtronic Model Number	Vitatron Family	Vitatron Model Number	U.S. PMA Number
P830061				
CapSure SP	4023	Excellence +	IMD49	P830061
CapSure Sense	4073	Crystalline	ICM 09	P830061
CapSure Sense	4074	Crystalline	ICM09B	P830061
CapSure SP Novus	4092	Excellence PS+	IMK49B	P830061
CapSure SP	4523	N/A	N/A	P830061
CapSure SP	4524	Excellence +	IMD49JB	P830061
CapSure Sense	4574	Crystalline	ICM09JB	P830061
CapSure SP Novus	4592	Excellence PS+	IMK49JB	P830061
P850059				
CapSure SP Novus	5092	Excellence SS+	IML49B	P850059
CapSure Z Novus	5054	Impulse II	IHP09B	P850089
CapSure Z Novus	5554	Impulse II	IHP09JB	P850089
CapSure SP Novus	5592	Excellence SS+	IML49JB	P850089
CapSure SP Novus	5594	N/A	N/A	P850089
P920015				
Sprint	6943	N/A	N/A	P920015
Sprint Quattro	6944	N/A	N/A	P920015
Sprint	6945	N/A	N/A	P920015
Sprint Quattro	6947	N/A	N/A	P920015
P930039				
CapSure Fix	4067	Pirouet +	IMU49	P930039
CapSure Fix	4068	Pirouet +	IMU49B	P930039
CapSure Fix	4568	Pirouet +	IMU49JB	P930039
CapSure Fix	5067	Pirouet S+	IMX 49	P930039
CapSure Fix	5068	Pirouet S+	IMX49B	P930039
CapSure Fix Novus	5076	Crystalline	ICF09B	P930039
CapSure Fix	5568	Pirouet S+	IMX49JB	P930039
P980016				
CapSure Fix	6940	N/A	N/A	P980016

2. Reason for Change

Medtronic pursued a supplier change of (b)(4) to honor (b)(4) request to limit the use of their materials in chronically implanted medical devices.

3. Rationale for Implementation via the 30-day Notice

According to 21 CFR 814.39(e), the supplier change Medtronic intends to implement involves a change to a manufacturing method or process that falls within those that qualify for submission as a 30-day PMA Supplement, to compensate for a change in suppliers of raw material or components. Additionally, the change is consistent with FDA's Guidance for Industry and CDRH: *30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes*. The change does not involve a change to the product specification, nor to PMA designate physical or chemical specifications of the finished product; however, Medtronic views the use of the (b)(4) as a material that is critical to the performance of the device which therefore, qualifies the change as a 30-Day Notice.

This strategy has previously been discussed with FDA. Past communication records are attached as **Attachment E.**

In addition, the same strategy was taken and accepted by FDA for the change of the (b)(4) and (b)(4) versions of this material (P830061/S032, P850089/S047, P890003/S064, P900061/S045, P920015/S023, P930039/S010, P950024/S004, P980016/S019, and P980050/S007 –approved August 8, 2001).

4. Summary of Data or Information Supporting the Change

The following testing was conducted to substantiate the modification of an alternate supplier:

A. Characterization testing consisted of mechanical, electrical, chemical, and extraction testing. **Attachment A**.
B. Applicable biocompatibility testing was conducted on the (b)(4) in accordance with the guidelines outlined in the International Standard ISO-10993, Biological Evaluation of Medical Devices –Part 1 and FDA Blue Book Memorandum-G95-1. **Attachment B.**
C. Material Quality Assurance Testing of the (b)(4). **Attachment C.**
D. Design Assurance Testing of leads. This testing was conducted on a representative number of leads that encompasses the following lead designs: low voltage and high voltage, passive and active fixation, straight and pre-formed (b)(4) (b)(4) (b)(4) leads. The lead models were chosen because they are representative of all Medtronic leads that are affected by this change. **Attachment D.**
E. A letter from (b)(4) authorizing FDA permission to access the (b)(4) Master File, is included as **Attachment F.**

Additionally, testing followed the outline provided in the *Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions. issued on November 1, 2000*. Particular attention was given to Attachment A: (b)(4) (b)(4)

Responses to the applicable bullet points from 30-Day Notice Guidance Document

- **A summary of the procedures established for the identification, documentation, validation, review and approval of the manufacturing changes covered by the notice.**

  Not applicable. There are no lead manufacturing changes affected.

- **If the changed procedures are to be routinely verified by sampling and independent measurement, summarize the statistical rationale for the sampling method.**

  Not applicable. There are no procedures changing and the supplier change does not require verification through sampling.

- **If the changed procedures are validated, the process parameters should be monitored and controlled. The 30-day notice should summarize how this will be done.**

  Not applicable. The supplier change is not a process or procedure change and therefore, did not require validation in which the parameters required monitoring and controlling.

- **A summary of the completed validation study that demonstrates that the manufacturing change can be made without significantly changing the final device operation.**

  Validation was not conducted because there were no lead manufacturing changes as a result of the supplier change.

- **If the manufacturing change involves changes in components or raw material, a summary of the procedures established for evaluation of new suppliers, if any. Describe the type and extent of control to be exercised over the component or raw material, including specifications for the incoming material.**

  This change does not involve a change in components or raw materials; rather, it involves a change to a supplier of a raw material. The same incoming inspection tests apply to the new supplier. (b)(4) from both suppliers meets the current material specification for (b)(4) which has not changed); however, a new specification was created for (b)(4) to allow for phase in of the material from the new supplier. Components made from the (b)(4) meet the component specification, and final device operation and testing was conducted and is provided as part of this submission.

- **If the change involves use of a new contractor for manufacturing or quality control testing, a summary of the procedures and criteria established for evaluation of that contractor.**

  Not applicable. The supplier change was not implemented for manufacturing or quality control testing on a device level.

- **Summarize the change controls necessary for modifying the manufacturing or quality control instructions or specifications for the device.**

  There are no changes to the manufacturing or quality control instructions or specifications for the devices. However, implementation of the supplier change is

controlled by initiating an Engineering Change Order (ECO). The ECO will not be signed off until Medtronic receives FDA approval of the 30-day notice.

5. **Statement of Conformity to the Requirements of the Quality System/GMP Regulations**

To the best of our knowledge, the facilities in which these products are manufactured conform to the Quality System / GMP regulation (21 CFR 820) regarding change control, validation, and document control.

ATTACHMENTS:

Attachment A	(b)(4)
Attachment B	
Attachment C	
Attachment D	(b)(4)
Attachment E	
Attachment F	

Medtronic considers the contents of this PMA-S 30-day Notice to be **CONFIDENTIAL.** Medtronic respectfully requests that this information be given the maximum protection provided by law.

Sincerely,

MEDTRONIC, INC.

Kristy K. Mollner, RAC
Sr. Regulatory Affairs Specialist
Cardiac Rhythm Management
Telephone: (763) 514-4189
Fax: (763) 514-6424
E-mail: kristina.mollner@medtronic.com

P920015/S27/A1: C1

Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576
www.medtronic.com

tel 763.514.4000

March 25, 2003

Food and Drug Administration
Office of Device Evaluation
Document Mail Center (HFZ-401)
ATTN: 30-day Notice
9200 Corporate Blvd.
Rockville, Maryland 20850

CC: Food and Drug Administration
Office of Compliance
Field Programs Branch (HFZ –306)
ATTN: 30-day Notice
2098 Gaither Road
Rockville, Maryland 20850

RE: Amendment 1: 30-DAY NOTICE PMA Supplement to the following:
P830061 / S036
P850089 / S052
P920015 / S027
P930039 / S015
P980016 / S034

Dear Ms Scott,

As requested in your email communication to me on March 24, 2003, enclosed is Amendment 1 to the above referenced PMA Supplements. This Amendment addresses questions asked by FDA on March 24, 2003.

Pursuant to 21 CFR 814.39, this Amendment is being submitted in triplicate (One copy provided to the Office of Compliance and 2 copies provided to the Office of Device Evaluation).

Medtronic considers the contents of this Amendment to be **CONFIDENTIAL.** Medtronic respectfully requests that this information be given the maximum protection provided by law.

Sincerely,

MEDTRONIC, INC.

Kristy K. Mollner, RAC
Sr. Regulatory Affairs Specialist
Cardiac Rhythm Management
Telephone: (763) 514-4189
Fax: (763) 514-6424
E-mail: kristina.mollner@medtronic.com

Sp 6

RESPONSES TO MARCH 24, 2003, QUESTIONS

1. **Please summarize the steps you took, based on your change control procedures, to identify, document, review and approve this change involving the addition of an alternate supplier.**

   As stated in the PMA-S submitted on March 3, 2003, Medtronic will implement this change by initiating an (b)(4) (b)(4) This (b)(4) will not be signed off until Medtronic receives FDA approval of the 30-day notice. This same process was followed for implementation of the supplier change for the (b)(4) (b)(4) (b)(4) (P830061/S032, P850089/S047, P890003/S064, P900061/S045, P920015/S023, P930039/S010, P950024/S004, P980016/S019, and P980050/S007), approved August 8, 2001.

   (b)(4) (b)(4)

   Specifically, in regard to the (b)(4) (b)(4) material, a new part number was created to simplify traceability. The (b)(4) (b)(4) specification was created by using the (b)(4) (b)(4) specification as a model. This specification is for the (b)(4) (b)(4) raw material resin, which includes all (b)(4) (b)(4) (b)(4) (b)(4) materials were implemented under a separate PMA-S as specified above. This (b)(4) (b)(4) raw material (b)(4) specification was initially development released per the (b)(4) (b)(4) for purposes of qualification activities. Upon FDA approval of the (b)(4) (b)(4) Material Supplier change, the raw material (b)(4) specification was (b)(4) production released. This (b)(4) also converted the (b)(4) material to inactive status since qualification and approval of the (b)(4) material had not been completed. All testing for the (b)(4) material has since been completed (e.g., MQA, characterization, Reliability Assurance, Biocompatibility) and results of this testing were provided in the PMA-S submitted March 3, 2003. After receiving FDA approval to use the (b)(4) (b)(4) material in product, the (b)(4) (b)(4) raw material (b)(4) specification will be (b)(4) (b)(4) changed to convert the (b)(4) (b)(4) from inactive status to active production released status.

2. **Please summarize the procedures you used to evaluate your new supplier.**

Medtronic took the following steps for evaluation of (b)(4) as an alternate supplier of the (b)(4) These steps are consistent with Medtronic's Quality Assurance Instructions for Supplier Quality Assessment.

(b)(4) **Assessment:**

On-site appraisals of (b)(4) quality / business system were made to determine their capability to provide Medtronic with (b)(4) that meets Medtronic's requirements.

(b)(4) **Quality System Audits:**

A systematic, on-site Medtronic examination of (b)(4) quality system (including manufacturing process and systems) was performed to determine (b)(4) ability to meet Medtronic's requirements. Audits are conducted by Medtronic on a periodic basis.

(b)(4) **Evaluation:**

Each (b)(4) received from (b)(4) is subjected to standard incoming inspection procedures to assure compliance to specification attributes. This inspection was also performed on the original 3 qualification lots and is summarized on page (b)(4) of the PMA-S.

Processability:

The ability of the (b)(4) to be processed into (b)(4) and into (b)(4) was verified. Multiple (b)(4) lots were produced from multiple raw material (b)(4) by approved Medtronic suppliers, and then tested per standard inspection procedures against the relevant specifications.

(b)(4) were then fabricated from the qualified raw material (b)(4) and built into finished leads and subassemblies for verification testing. The results of this testing is included on page (b)(4) of the PMA-S.

P20015/S27/A1/C2

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 26, 2003

KRISTY K. MOLLNER
MEDTRONIC, INC.
7000 CENTRAL AVE. N.E.
MINNEAPOLIS, MN 55432

Dear MS. MOLLNER:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your PMA AMENDMENT. This PMA AMENDMENT has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

PMA Number: P920015/S027/A001
Dated: 25-MAR-2003
Received: 26-MAR-2003
Device: SPRINT/SPRINT QUATTRO

Any questions concerning this submission should be directed to the undersigned at (301)443-8320. All future correspondence regarding this PMA should be identified with the PMA number assigned above and should be submitted with the required number of copies to:

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

Sincerely yours,

-A-

Janet L. Donelson
Assistant Director for Program Operations
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Pages removed for the following reason: Duplicate pages

Pages removed for the following reason: Duplicate pages