



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT - 3 2007

Kristina Simmons  
Medtronic, Inc.  
Cardiac Rhythm Disease Management  
1015 Gramsie Road  
Shoreview, MN 55126

Re: P030036  
SelectSecure™ Lead Model 3830  
Procode: NVY

Dear Ms. Best:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) sent you the enclosed approval order on August 3, 2005 for the above referenced premarket approval application (PMA). We have discovered that your letter erroneously reflected a product code of NVN instead of NVY. Thus, the purpose of this letter is to inform you that the correct product code for your approved PMA is NVY.

If you have any questions about this correction, please contact Ms. Samie Allen at 240-276-4013.

Sincerely yours,

A handwritten signature in cursive script that reads "Samie Allen".

Samie Allen

Acting Director

Premarket Approval Application Program

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure



AUG - 3 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Medtronic, Inc  
c/o Ms. Kristina Simmons  
Sr. Regulatory Affairs Specialist  
7000 Central Avenue NE  
Minneapolis, MN 55432-3576

Re: P030036  
SelectSecure™ Lead Model 3830  
Filed: September 10, 2003  
Amended: October 9, 30, and 31, and November 3, 2003; March 2, April 30, July 12,  
September 13, November 24, 2004, and April 15, 2005  
Procode: NVN

Dear Ms. Simmons:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Medtronic® SelectSecure™ Lead Model 3830. The Model 3830 lead has applications where implantable atrial or ventricular, single-chamber or dual-chamber pacing systems are indicated. The Model 3830 lead is intended for pacing and sensing in the atrium or ventricle. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval for Cardiac Pacemakers and Programmers" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the post approval requirements outlined in the enclosure, you have agreed to the following post-approval conditions:

1. To further improve your manufacturing specifications, as outlined in our email dated July 12, 2005, you have agreed to work with FDA to address issues related to finished product specifications, test methods per the July 12 email, product release testing, in vivo-in vitro correlations, and the certificate of analysis for the 3830 lead.
2. You should monitor any revisions made to the BDP labeling for changes that may be relevant to the Medtronic 3830 lead. Specifically, you should report annually all relevant changes made to the warnings, precautions or adverse event sections of the BDP label. Further, you should evaluate whether any of the changes made to the BDP label warrant changes to the Medtronic 3830 lead. You should submit any needed changes to the Medtronic 3830 instructions for use to FDA.

Expiration dating for this device has been approved at six months.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

Page 3 – Ms. Kristina Simmons

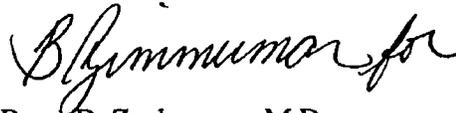
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

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

If you have any questions concerning this approval order, please contact Vivianne Holt at 301-443-8243 x 170.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Last modified 1-31-02

CONDITIONS OF APPROVAL  
FOR CARDIAC PACEMAKERS AND PROGRAMMERS

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e) or (f). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report (see below). FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

Alternate submissions permitted under 21 CFR 814.39(f) for manufacturing process changes include the use of a 30-day Notice. The manufacturer may distribute the device

30 days after the date on which the FDA receives the 30-day Notice, unless the FDA notifies the applicant within 30 days from receipt of the notice that the notice is not adequate.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

In addition to the above and in order to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use, the annual postapproval reports shall include, separately for each model number (if applicable), the following information known by or reported to the applicant:

(1) The number of pacemakers domestically implanted and the number of reported explants and deaths.

(2) A breakdown of the reported deaths into pacemaker related and non-pacemaker related.

(3) A breakdown of the reported explants into the numbers reported at end of battery life, having complications unresolvable by programming and for other reasons with safety and effectiveness issues which can be derived from the reports stated.

(4) The number of pacemakers returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion and failed, with the failure mechanisms described.

(5) A cumulative survival table for the pacemakers.

(6) The number of programmers and modules shipped and the number of returns with a breakdown into the numbers currently in analysis, operating properly and failed, with the failure mechanisms described.

**ADVERSE REACTION AND DEVICE DEFECT REPORTING.** As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mix-up of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual

Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

#### REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR)

REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

- (1) May have caused or contributed to a death or serious injury; or
- (2) Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc. Any written report is to be submitted to:

Food and Drug Administration  
Center for Devices and Radiological Health  
Medical Device Reporting  
PO Box 3002  
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336) and FDA publications entitled “An Overview of the Medical Device Reporting Regulation” (FOD # 509) and “Medical Device Reporting for Manufacturers” (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH’s Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH’s Division of Small Manufacturers International and Consumer Assistance (DSMICA) at 301-443-8818.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG - 4 2005

Medical Device Tracking Order

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville MD 20850

Ms. Kristina Simmons, M.S., R.A.C.  
Senior Regulatory Affairs Specialist  
Medtronic, Inc.  
7000 Central Avenue NE  
Minneapolis, Minnesota 55432-3576

RE: PMA No. P030036 Cardiovascular permanent implanted pacemaker electrode

Dear Ms. Simmons:

You are notified by this letter of your obligation to adopt a method of tracking for the devices referenced above, as authorized by section 519(e) of the Federal Food, Drug, and Cosmetic Act, (the Act) as amended by section 211 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The implementation of section 519(e) of the Act, as amended, requires the Food and Drug Administration (FDA) to issue an order to manufacturers when FDA determines that a person who manufactures and distributes a device meets the relevant statutory requirements and tracking is required to protect the public health. This order is effective immediately.

Section 519(e) of the Act, as amended, states that FDA, "...may by order require a manufacturer to adopt a method of tracking a class II or class III device—

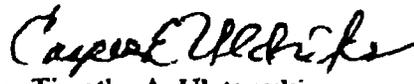
- (A) the failure of which would be reasonably likely to have serious adverse health consequences; or
- (B) which is—
  - (i) intended to be implanted in the human body for more than one year, or
  - (ii) a life sustaining or life supporting device used outside a device user facility."

As you know, the corresponding medical device tracking regulations, found in Title 21 Code of Federal Regulations (CFR) Part 821, are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person by whom the device is intended to be used when patient notification (under section 518(a) of the act) or device recall (under section 518(e) of the act) actions are ordered by the agency. The device tracking requirements for exemptions and variances, system and content requirements of tracking, the obligations of persons other than device manufacturers, such as distributors, records and inspection requirements, confidentiality, and record retention requirements, which were published in the Federal Register on August 16, 1993, remain in effect. (21 CFR sections 821.2, 821.25, 821.30, 821.50, 821.55 and 821.60, copy enclosed.)

Page 2 – Medtronic Inc.

This order to adopt a tracking method does not change your obligations concerning other existing FDA regulations affecting your device. FDA published in the Federal Register on February 28, 2002, an amendment to the final rule to revise the scope of the regulation and add certain patient confidentiality requirements, and non-substantive changes to remove outdated references and simplify terminology. (67 FR 6943) Please contact Chet Reynolds in the Office of Compliance at (240) 276-0157 ext. 165 if you need specific guidance. Other general information on your responsibilities under the Act, or more specific information, such as non-binding guidance on medical device tracking, may be obtained from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at the internet address [www.fda.gov/cdrh](http://www.fda.gov/cdrh).

Sincerely yours,

*for* 

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

Enclosure