DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Ms. Deborah Kidder
Principal Regulatory Affairs Specialist
Medtronic, Inc
8200 Coral Sea Street, MVS11
Mounds View, MN 55112

Re: P090013
Revo MRI SureScan Pacing System
Filed: June 9, 2009
Amended: July 1, 2009; July 27, 2009; September 4, 2009; November 12, 2009; November 16, 2009; December 14, 2009; February 1, 2010; March 8, 2010; June 7, 2010; June 15, 2010; September 7, 2010; January 13, 2011
Procodes: LWP, NVN

Dear Ms. Kidder:

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 Revo MRI SureScan Pacing System, which consists of the Medtronic Revo MRI™ SureScan™ Model RVDR01 IPG, the Medtronic CapSureFix MRI™ SureScan™ 5086MRI lead, and the Revo MRI™ Software Application Model SW018. This system is indicated as follows:

> The Medtronic Revo MRI™ SureScan™ Model RVDR01 IPG is indicated for use as a system consisting of a Revo MRI SureScan IPG implanted with two CapSure Fix MRI™ SureScan™ 5086MRI leads. A complete system is required for use in the MRI environment.
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> The Medtronic Revo MRI™ SureScan™ Model RVDR01 IPG is indicated for the following:
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> - Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity
>
> - Accepted patient conditions warranting chronic cardiac pacing include:

- symptomatic paroxysmal or permanent second-degree or third-degree AV block
- symptomatic bilateral bundle branch block
- symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders
- bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias

The device is also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output
- VVI intolerance (for example, pacemaker syndrome) in the presence of persistent sinus rhythm

Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmia in bradycardia patients with one or more of the above pacing indications.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmia in bradycardia patients with atrial septal lead placement and one or more of the above pacing indications.

The Medtronic CapSureFix MRI™ SureScan™ 5086MRI lead is indicated for use as a system consisting of a Medtronic Revo MRI™ SureScan™ Model RVDR01 IPG implanted with two SureScan leads. A complete system is required for use in the MRI environment. This lead has application where implantable dual chamber MR Conditional pacing systems are indicated.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 18 months for the RevoMRI SureScan Model RVDR01 IPG and 24 months for the CapSureFix MRI SureScan 5086MRI lead.

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition, because your device is a pacemaker, implantable cardioverter-defibrillator (ICD), or system lead, FDA has determined that the following additional information is necessary to provide continued reasonable assurance of the safety and effectiveness of the device. In the Annual Report, provide the following information known by or reported to the applicant:

1. The number of pacemakers/pulse generators/leads domestically implanted and the number of reported explants and deaths.

2. A breakdown of the reported deaths into pacemakers/pulse generators/leads related and non-pacemaker/pulse generator/leads related.

3. A breakdown of the reported explants into the number reported that were:

    a. For pacemakers and pulse generators: at end of battery life, the number that had complications not resolvable by programming, and, as applicable, the numbers that experienced other safety and effectiveness complications as ascertained by the user, applicant, or otherwise, or

    b. For leads: associated with mechanical failure, associated with clinical complications, and as applicable, the numbers that experienced other safety and effectiveness complications as ascertained by the user, applicant, or otherwise.

4. The number of pacemakers/pulse generators/leads returned to the applicant for cause from domestic sources, with a breakdown into:

   a. For pacemakers and pulse generators: the number currently in analysis, the number operating properly, and the number at normal battery depletion and failed (with the failure mechanisms described).

   b. For leads: the number currently in analysis, the number operating properly, the number failed (with failure mechanisms described); broken down into groupings for full leads and partial leads.

5. A cumulative survival table for the pacemakers/pulse generators/leads.

In addition to the Annual Report requirements, you have agreed to provide the following data in post-approval study reports (PAS). As a condition of approval, you have agreed to conduct the following post-approval study of Chronic Lead Performance and Multiple MRI Scans for the REVO SureScan Pacing System.

The study is global, non-randomized, multi-center cohort study of patients undergoing implantation of the SureScan Pacing System. The study will include two arms 1) the Chronic Lead Performance Arm and 2) the Multiple MRI Scan Arm:

1. The Chronic Lead Performance Arm will consist of
   a. a prospective study design to characterize chronic lead performance following device implant, as well as a robust process to retrospectively collect implant data for each study subject;
   b. a post-approval study duration of at least 5 years;
   c. a sample size of 1,810, accounting for estimated attrition, which will be derived from subjects enrolled pre-implant and post-implant with a minimum of 50% of the total enrollment originating from the pre-implant cohort, results in a 2-sided 95% upper confidence bound of no more than 1.0% for individual adverse event rates, assuming an expected rate of 0.4%, using the exact binomial;
   d. enrollment plan which attempts to fully enroll the study within 30 months;
   e. a primary safety endpoint as Model 5086MRI leads that are placed in the right ventricle complication-free rate greater than 92.5% at 5 years, with any clinical adverse events omitted from the primary endpoint collected and reported as secondary data;
   f. a primary safety endpoint as Model 5086MRI leads that are placed in the right atrium complication-free rate greater than 92.5% at 5 years, with any clinical adverse events omitted from the primary endpoint collected and reported as secondary data;
   g. a rigorous process to monitor the status of all study subjects, to actively follow-up missed visits, and to document the reason for all subject dropouts;
   h. inclusion of a trend analysis process in the protocol to provide a robust early warning

mechanism to identify, characterize, and report adverse events, failure modes, and failure rates;

i. post-approval study status reporting at least every 6 months and a mechanism for providing non-scheduled trend analysis reports for new information;
j. inclusion of a full list of complications, failure modes, and definition of terms within the study protocol; and
k. collection of secondary data including implant data, demographic information, all reported adverse device effects, electrical performance, returned product analyses, extraction experience, and other parameters of interest.

2. Multiple MRI Scans Arm will consist of:
   a. enrollment of patients with a REVO SureScan system when they are indicated for a MRI scan, allowing for the enrollment of patients greater than 30 days post implant and the inclusion of EnRhythm MRI IDE subjects;
   b. a design which tests whether the MRI-related complication rate (as an Individual Failure Mode) will be less than 2%, i.e. the one-sided confidence interval upper bound is lower than 2% as a primary endpoint, where the MRI-related complication rate will be calculated by dividing the number of subjects with an MRI-related complication by the total number of subjects who experience at least one MRI scan;
   c. the characterization of the cumulative change in pacing capture thresholds (PCT) for subjects with multiple (2 or more) MRI scans.

FDA would like to remind you that you are required to submit PAS Progress Reports every six months. Please refer to the guidance document on how to handle post-approval studies imposed by approval orders, located at the following website:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm

Two copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA

Supplement Decision-Making Process"
(www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

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 would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, 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 www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. 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 submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

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. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by 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. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive (general information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm; clinical and statistical data: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm)

U.S. Food and Drug Administration
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If you have any questions concerning this approval order, please contact Owen Faris at (301) 796-6356.

Sincerely yours,

Christy Foreman

Christy Foreman
Acting Director
Office of Device Evaluation
Center for Devices and
Radiological Health