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

MAR 14 2011

Ms. Catherine M. Vitols
Principal Regulatory Affairs Specialist
Medtronic Neuromodulation
7000 Central Avenue, N.E.
MINNEAPOLIS MN 55432

Re: P080025
Medtronic® InterStim® Therapy System
Filed: September 26, 2008
Amended: November 26, December 22, 2008, July 2, 2009, and July 1, 2010
Procode: EZW

Dear Ms. Vitols:

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® InterStim® Therapy System. This device is indicated for the treatment of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments. 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.

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 to the Annual Report requirements, you have agreed to provide the following data in post-approval study reports (PAS). Two copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below.

You have agreed to continue follow-up of the patients enrolled in the premarket InterStim trial for five years. This post-approval study will continue to gather long-term performance data from the subjects currently enrolled in the clinical trial (G010206). The post-approval study will be called the "InterStim Sacral Nerve Stimulation Therapy for Bowel Control: **F**ecal **I**ncontinence **P**ost Approval **S**tudy (**FI-PAS**). The primary objective is to continue evaluation of incontinent episodes per week at yearly intervals through five years post-implant. Device and/or therapy related adverse events will be characterized through five years post implant. Secondary objectives to be evaluated include:

- Evaluation of the patient's quality of life at yearly intervals using the Fecal Incontinence Quality of Life (FIQOL) instrument through five years post implant;
- Evaluation of the number of incontinent days per week at yearly intervals through five years post implant;
- Evaluation of the number of urgent incontinent episodes per week at yearly intervals through five years post implant through five years post implant.
- Evaluation of the severity of the patient's fecal incontinence through completion of the Fecal Incontinence Severity Index (FISI) at yearly intervals through five years post implant;
- Evaluation of the patient's perception of their fecal incontinence through completion of the self-rated bowel health questionnaire at yearly intervals through five years post implant; and
- Evaluation of the severity of the patient's fecal incontinence through the documentation of pad use at yearly interval through five years post implant.

You agreed to conduct two sets of analysis; the per-protocol (completers) analysis and the adjusted worst-case analysis. The per-protocol analysis will include only those subjects who have bowel diaries at the follow-up visits in the analysis.

The adjusted worst case analysis is an intent-to-treat analysis which imputes missing data as follows:

- For patients who exit the study and/or have the device explanted due to a device or therapy related adverse event or due to lack of effectiveness or due to a death, their baseline diaries will be used as their follow-up data and therefore they will be considered failures.

- For patients who exit the study due to other reasons (i.e., site closure, patient-related adverse event, voluntary withdrawal from the study), and for patients who miss a study visit or fail to provide a bowel diary at the scheduled visit, the last-observation carried forward method will be used to impute the missing data.

Post-approval study reports will be submitted every six months for the first two years and then annually until the study is completed. The results of the post-approval study must be reflected in the labeling (via PMA supplement) when the study is completed.

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 Food and Drug Administration, Dockets Management Branch, (HFA-305), 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
Center for Devices and Radiological Health
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If you have any questions concerning this approval order, please contact Ms. Kathleen Olvey at 301-796-6525.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health