K062041

Appendix A: 510(K) Summary

Submitter

Medtronic, Inc.
710 Medtronic Parkway NE
Minneapolis, MN 55432

AUG 16 2006

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Date Prepared: July 18th, 2006

Name of Device

Trade Name: Medtronic Model 3875 1 x 8 SC Test Stimulation Lead
Common Name: Neurostimulation Trialing Lead
Classification: Class II
Product Code: GZB

Predicate Devices

The predicate devices for the Medtronic Model 3875 1 x 8 SC Test Stimulation Lead are the currently available Model 3873 1 x 8 Test Stimulation Lead and Model 3874 1 x 8 Compact Test Stimulation Lead.

Device Description

The Model 3875 1 x 8 SC is a test stimulation lead with accessories included in the kit. A test stimulation lead is a thin wire covered by an insulative coating, which is intended to be connected to a screening cable and to an external neurostimulator (ENS). The lead has small metal electrodes near its tip through which the ENS delivers electrical stimulation to an area where pain signals will be blocked.

Intended Use

The intended use and indications of the modified device, Model 3875 1 x 8 SC Test Stimulation Lead, as described in the labeling, are the same as the intended use and indications for Medtronic's unmodified predicate devices.

The Model 3875 1 x 8 SC Test Stimulation Lead is indicated as an aid in the management of chronic, intractable, unilateral or bilateral pain associated with the following:

- Failed Back Syndrome or Low Back Syndrome or Failed Back;

- Radicular Pain Syndrome or Radiculopathies resulting in pain secondary to Failed Back Syndrome;
- Post Laminectomy Pain;
- Unsuccessful Disk Surgery;
- Degenerative Disk Disease (DDD/ Herniated pain refractory to conservative and surgical interventions;
- Peripheral Causalgia;
- Epidural Fibrosis;
- Arachnoiditis or Lumbar Adhesive Arachnoiditis;
- Complex Regional Pain Syndrome (CRPS) or Reflex Sympathetic Dystrophy (RSD) or Causalgia; and,
- Multiple Back Surgeries

Additional Contraindication: The Medtronic Model 3875 1 x 8 SC Test Stimulation Lead Kit is contraindicated for long-term implantation. The lead **MUST BE REMOVED** within ten (10) days of implant.

Summary of Studies

In Vitro testing on the design of the Model 3875 1 x 8 SC has been previously performed and repeat testing was not deemed necessary to support equivalence to the predicate devices. This is documented for the Model 3875 1 x 8 SC Test Stimulation Lead in report 07TR.020 and report NDHF1174-90920, which are located in Appendix E and Appendix G respectively, and in the design history file, NDHF1174.

Sterilization

The Medtronic Model 3875 1 x 8 SC Test Stimulation Lead Kit is labeled STERILE. The Model 3875 1 x 8 SC Test Stimulation Lead Kits will be sterilized using the same 100% Ethylene Oxide (EtO) sterilization process as the predicate devices.

Biocompatibility

All materials used in the Model 3875 1 x 8 SC Test Stimulation Lead Kit are identical to the materials used in the predicate devices, Models 3873 and 3874 Test Stimulation Leads, and additional biocompatibility testing was not deemed necessary for the Model 3875 1 x 8 SC Test Stimulation Lead and accessory components. All device materials / components were assessed for biocompatibility consistent with ISO- 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" for the predicate devices. All materials were found to be biocompatible and in compliance to ISO 10993-1.

Conclusion

Through data and information presented, as well as similarity to legally marketed devices, Medtronic, Inc. considers the Model 3875 1 x 8 SC Test Stimulation Lead Kit to be substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2006

Ms. Paula Cordero
Senior Regulatory Affairs Specialist
Medtronic, Inc
710 Medtronic Parkway
Minneapolis, Minnesota 55604

Re: K062041
Trade/Device Name: Medtronic® 3875 1 × 8 SC Test Stimulation Lead
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted spinal cord stimulator for pain relief
Regulatory Class: Class II
Product Code: GZB
Dated: July 18, 2006
Received: July 19, 2006

Dear Ms. Cordero

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K 062041

Device Name: Medtronic® Model 3875 1 x 8 SC Test Stimulation Lead

Indications For Use: The Model 3875 1 x 8 SC Test Stimulation Lead is indicated as an aid in the management of chronic, intractable, unilateral or bilateral pain associated with the following:

- Failed Back Syndrome or Low Back Syndrome or Failed Back;
- Radicular Pain Syndrome or Radiculopathies resulting in pain secondary to Failed Back Syndrome;
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Additional Contraindication: The Medtronic Model 3875 1 x 8 SC Test Stimulation Lead is contraindicated for long-term implantation. The lead **MUST BE REMOVED** within ten (10) days of implant.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K062041