FEB 2 6 2010

510(k) Summary

Date Prepared October 9, 2009

Submitter

Medtronic
710 Medtronic Parkway NE
Minneapolis, MN 55432-5604
Establish Registration Number: 2135394

Contact Person

Mary E. Donlin
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Device Name and Classification

Trade Name:	Cardioblate® Surgical Ablation System
Common/Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	21 CFR 878.4400
Product Code:	GEI
Classification:	Class II

Predicate Device

Cardioblate® Surgical Ablation System (K080509)

Device Description

The Medtronic Cardioblate® Surgical Ablation System consists of a reusable radiofrequency generator which can be connected to hand-held monopolar or bipolar radiofrequency devices. The ablation devices are sterile, single-use devices operating in either monopolar or bipolar mode that deliver radiofrequency energy to the selected tissue.

Indications for Use

The Medtronic Cardioblate® System is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Comparison to Predicate Device

A comparison of the modified product and the currently marketed surgical ablation device has the following similarities to the system which received 510(k) clearance:

- Same indicated use
- Same operating principle
- Same radiofrequency generator and delivery system
- Similar patient-contacting materials, with the exception of the change in PVC formulation to remove DEHP
- Same shelf life for disposables
- Patient-contacting devices are packaged and sterilized using identical materials and processes

Labeling and Intended Use

The labeling and intended use are unchanged as a result of the modification to the saline line cable assembly. The Instructions for Use and Labeling can be provided upon request.

Summary of Performance Data

Biocompatibility and performance bench test data were used to establish the performance characteristics of the modifications to this device. Clinical testing was not required to establish substantial equivalence. The following performance tests were conducted:

- Biocompatibility Testing
- Accelerated Aging Study

Conclusion

The modifications to the saline line cable assembly used with the Cardioblate® Surgical Ablation device described in this submission result in a substantially equivalent device because the fundamental scientific principle, labeling, and the intended use are unchanged as a result of these device modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 2 6 2010

Medtronic Cardiovascular
c/o Mary E. Donlin
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K093203
Trade/Device Name: Cardioblate Surgical Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 29, 2009
Received: January 29, 2010

Dear Ms. Donlin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

5 10(k) Number: _____

Cardioblate®Surgical Ablation System, consisting of the Cardioblate®68000 Generator (K060400) and the following ablation devices:
Cardioblate®BP2 Surgical Ablation Device, Model 60831 and 68031 (K060400 & K080509)
Cardioblate®LP Surgical Ablation Device, Model 60841 (K060400)

Indications for use:

The Medtronic Cardioblate® System is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

- These devices are already labeled with the proposed indication statement.

Prescription Use ___X____ **OR** **Over-The-Counter-Use _____**
(Part 21 CPR 801 Subpart D) **(Part 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 Cardiovascular Devices

510(k) Number K093203