JUN 14 2012 K121451

510(k) Summary of Safety and Effectiveness

Date Prepared:	**May 11, 2012**
Applicant:	Medtronic, Inc. 710 Medtronic Parkway, NE Minneapolis, MN 55432-5604 **Establishment Registration No.** 2135394
Contact Person:	Mary Donlin Senior Regulatory Affairs Specialist Phone: (763) 526-9172 Fax: (763) 367-8147 E-mail: mary.e.donlin@medtronic.com
Trade Name:	Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device, Model 49205 (K090721)
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification:	Class II, 21 CFR 878.4400 Class II, 21 CFR 870.3680
Product Code:	OCL LDF
Name of Predicate Device:	Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device, Model 49205 (K090721)

Device Description:

The Medtronic Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device is a hand-held, monopolar, radiofrequency ablation device powered by the Cardioblate® 68000 Generator. It has a saline irrigation system that delivers fluid at the contact point between tissue and electrode tip to cool tissue during radiofrequency energy delivery. The device can also be used with the Medtronic Model 2090/2290Programmer/Analyzer and the Medtronic Model 5388/5348 External Temporary Pacemaker for bipolar sensing of the ventricle or the atrium and bipolar stimulation (pacing) of the atrium. The device is intended for intermittent operation. The device is provided sterile, nonpyrogenic, disposable, and for single use only.

Intended Use:

The Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device is a sterile, single use electrosurgery device intended to ablate cardiac tissue using radiofrequency energy when connected to the Cardioblate® 68000 Generator or for temporary cardiac pacing, sensing, recording, and stimulation

during the evaluation of cardiac arrhythmias during surgery when connected to an external temporary cardiac pacemaker.

Contraindications:
The Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device should not be used for patients that have active endocarditis at time of surgery. The device is contraindicated for ablation in a pool of blood (e.g. through a purse string suture on a beating heart). Effects of this type of ablation have not been studied.

Substantial Equivalence:
The historical changes in this submission did not involve changes to control mechanism, operating principles, energy type, indications or sterilization process. None required clinical evidence to evaluate impact to safety and effectiveness. The changes were considered to be routine changes to maintain or improve device performance based on internal or external feedback and the information generated as part of design verification and validation activities or technical assessments confirmed these changes did not adversely the device's safety or effectiveness.

Conclusion:

The modifications to the Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device described in this submission have not altered the fundamental scientific or indication of the device. The current device is substantially equivalent to the previously submitted and approved predicate Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device, Model 49205 (K090721).

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

JUN 14 2012

Medtronic, Inc.
c/o Ms. Mary Donlin
Senior Regulatory Affairs Specialist
710 Medtronic Parkway, NE
Minneapolis, MN 55432

Re: K121451
Trade/Device Name: Cardioblate MAPS Surgical Mapping, Ablation, Pacing, ans Sensing Device, Model 49205
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II (two)
Product Code: OCL, LDF
Dated: May 15, 2012
Received: May 16, 2012

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

K121451

Statement of Indications for Use

510(k) Number: **K12XXXX**

Device Name:

Medtronic Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device, Model 49205

Indications for use:

The Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device is a sterile, single use electrosurgery device intended to ablate cardiac tissue using radiofrequency energy when connected to the Cardioblate® 68000 Generator or for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to an external temporary cardiac pacemaker.

Prescription Use __X__ or Over-The-Counter Use _____

Per 21 CFR 801.109

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

Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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