K121767

510(k) Summary of Safety and Effectiveness

Date Prepared:	**June 14, 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® Gemini® Surgical Ablation Device, Models 49260/49261 (**K080509**)
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification:	Class II, 21 CFR 878.4400
Product Code:	OCL
Name of Predicate Device:	Cardioblate® Gemini® Surgical Ablation Device, Models 49260/49261 (**K080509**)

JUL 13 2012

Device Description:

The Medtronic Cardioblate® Gemini® Surgical Ablation Device is a hand-held, single-use, bipolar, radiofrequency ablation device intended to ablate cardiac tissue during cardiac surgery. It has a saline irrigation system to deliver fluid at the contact point between the tissue and electrode to cool the tissue during radiofrequency energy delivery and is intended for intermittent operation. Two unique jaw curvatures are provided: a standard curve (Model 49260) and extra curve (Model 49261). The device is provided sterile, nonpyrogenic, disposable, and for single use only.

Intended Use:

The Cardioblate® Gemini® Surgical Ablation Device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy. The system is indicated for use, under direct or endoscopic visualization, in surgical procedures, including minimally invasive surgical procedures.

Contraindications:
The Cardioblate® Gemini® Surgical Ablation 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. The information generated as part of design verification and validation activities or technical assessments confirmed these changes did not adversely affect the device's safety or effectiveness.

Conclusion:
The modifications to the Cardioblate® Gemini® Surgical Ablation Device, described in this submission, have not altered the fundamental scientific technology or indications for use of the device. The current device is substantially equivalent to the previously submitted and approved predicate Cardioblate® Gemini® Surgical Ablation Device, Models 49260/49261 (**K080509**).

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

JUL 13 2012

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

Re: K121767
Trade/Device Name: Cardioblate Gemini Surgical Ablation Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II (two)
Product Code: OCL
Dated: June 14, 2012
Received: June 15, 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

K121767

Indications for Use

510(k) Number (if known): K121767

Device Name: Cardioblate Gemini Surgical Ablation Device

Indications For Use:

The Cardioblate® Gemini® Surgical Ablation Device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy. The system is indicated for use, under direct or endoscopic visualization, in surgical procedures, including minimally invasive surgical procedures.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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