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K060400

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510(k) SUMMARY of Safety and Effectiveness

(In accordance with SMDA of 1990 and pursuant with 21 CFR 807.92)

I. Applicant Information:

Date Prepared:	February 3, 2006
Submitter:	Medtronic, Inc.
Address:	710 Medtronic Parkway, NE Minneapolis, MN 55432-5604
Establishment Registration No.	2135394
Contact Person:	David D. Cox, Ph.D. Senior Principal Regulatory Affairs Specialist
Telephone Number:	(763) 391-9251
Fax Number:	(763) 391-9279

II. Device Information:

Trade Name: Cardioblate® 68000 Generator

Common Name: Cardioblate® Surgical Ablation System, which consists of:

- Cardioblate® 68000 Generator

Which can be used with:

- Cardioblate® BP2 Surgical Ablation Device, model 60831
- Cardioblate® LP Surgical Ablation Device, model 60841
- Cardioblate® Monopolar Pens (K013392)

Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification:	Class II, 21 CFR 878.4400
Product Code:	GEI

Predicate Device: Cardioblate® Bipolar Radiofrequency Ablation System
510(k) No. K031247, Reg. No. 878.4400; Product Code: GEI

Predicate Device Intended Use: The Medtronic Cardioblate® System is intended to ablate soft tissue during general surgery using radiofrequency energy.

Device Description:	The Medtronic Cardioblate® 68000 Generator is a reusable, non-sterile radiofrequency generator. In bipolar mode, the generator is attached to a bipolar Surgical Ablation Device (e.g. Model 60831 or 60841), which is the hand-held, sterile, single-use device that applies radiofrequency energy to the selected tissue. The Cardioblate® 68000 Generator is capable of delivering a controlled amount of radiofrequency energy for both Monopolar and Bipolar surgical ablation techniques. The generator delivers up to 50 Watts energy in either the bipolar or monopolar mode.
Intended Use:	The Cardioblate® Surgical Ablation System is intended to ablate soft tissue during general surgery using radiofrequency energy.
Contraindications:	The Cardioblate® Surgical Ablation System is contraindicated for patients that have active endocarditis at the time of surgery.
Comparison to Predicate Device:	The Cardioblate® Surgical Ablation System with the model 68000 Generator is substantially equivalent to the Cardioblate® Surgical Ablation System with the Model 60890 Generator cleared by K031247. The Generator uses the same energy source to deliver the same amount of radiofrequency energy to ablate tissues, and uses the same surgical ablation devices. Although both generators use the same algorithms to operate, the Model 68000 Generator is updated to include a touchscreen interface, an updated microprocessor and a molded, ergonomic case.
Test Data:	Verification and validation testing confirms that the functional characteristics of the Cardioblate Surgical Ablation System with the Cardioblate® 68000 Generator are substantially equivalent to the predicate devices cited. This included software validation, hardware qualification, electromagnetic compatibility and safety testing on the generator, and lesion equivalence and transmurality equivalence tests on tissue with the entire system.
Summary:	Based on the technical information, intended use, laboratory verification tests and *in vitro* performance information provided, the system which includes the Cardioblate® 68000 in substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2006

Medtronic, Inc.
c/o Ms. Silvia Ankova
Senior Project Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K060400
Trade/Device Name: Medtronic Cardioblate® 68000 Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 10, 2006
Received: February 15, 2006

Dear Ms. Ankova:

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.

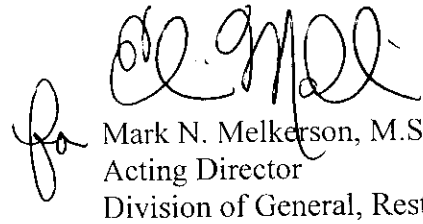
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Statement of Indications for Use

510(k) Number: K060400

Device Name: Medtronic Cardioblate® 68000 Generator

Indications for use:

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

Prescription Use ___x___ **OR** **Over-The-Counter-Use** _____
(Part 21 CFR 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 General, Restorative, and Neurological Devices

510(k) Number K060400