K013392

510(k) Summary of Safety and Effectiveness

JAN 2 5 2002

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Application Information:

Date Prepared:	January 8, 2002
Submitter:	Medtronic, Inc.
Address:	710 Medtronic Parkway, NE Minneapolis, MN 55432-5604
Establishment Registration No.	2135394
Contact Person:	Scott Cundy Sr. Regulatory and Quality Manager
Telephone Number:	(763) 391-9941
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Device Information:

Trade Name:	Medtronic® Cardioblate™ Radiofrequency Ablation System
Common Names:	Cardioblate™ System, which is made up of Cardioblate™ Surgical Ablation Pen & Cardioblate™ Surgical Ablation Generator
Classification Name:	Electrosurgical Cutting, and Coagulation Device and Accessories
Classification:	Class II, 21 CFR 878.4400
Predicate Devices:	TissueLink™ Floating Ball (K010662), Boston Scientific Cobra RF System (K010956), EndoCare Cryocare Cardiac Surgical System (K011040), AFx Microwave Flex Ablation Wand System (K003978), and ValleyLab Force 2 Electrosurgical Generator (K921884).
Device Description:	The Medtronic Cardioblate System is comprised of a radiofrequency ablation pen, radiofrequency generator, and accessories for the application of radiofrequency energy to tissue. The Cardioblate Pen is a hand-held, unipolar, radiofrequency surgical ablation pen for use during open-heart surgery. The Cardioblate Generator is capable of delivering the controlled radiofrequency energy that is required for the creation of linear lesions during open-heart surgery. The Cardioblate Generator

	delivers up to 50 Watts to the delivery device with a 20 – 500 Ohm range.
Intended Uses:	The Medtronic Cardioblate System is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.
Contraindications:	The Medtronic Cardioblate System is contraindicated for patients with active systemic infection or patients that have active endocarditis at time of surgery.
Nonclinical Performance:	The performance characteristics of the Medtronic Cardioblate System were tested and compared to the performance specifications of the listed predicate devices through both bench testing and non-bench analyses.
Substantial Equivanlence Conclusion:	For the intended use listed above, the Medtronic Cardioblate System is considered substantially equivalent to the listed predicate devices. The differences that do exist are believed to be minor and not raise any concern regarding the overall safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2002

Mr. Scott Cundy
Senior Product Regulation Manager
Medtronic, Inc.
Medtronic Cardiac Surgery Technologies
7601 Northland Drive
Minneapolis, Minnesota 55428

Re: K013392
Trade/Device Name: Medtronic® Cardioblate™ Radiofrequency Ablation System
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 8, 2002
Received: January 10, 2002

Dear Mr. Cundy:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Cardioblate Radiofrequency Ablation System
510(k) Number (if known): K013392

Indications for Use:

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

(Please do not Write below this line - continue on another page if needed)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:
or
Prescription Use: ✓
(Per 21 CFR 801.109)

(optional format 1-2-96)

for Mark N Milhersen
(Division Sign-Off)
Division of General, Rest ative
and Neurological Device

510(k) Number K013392