

FEB 26 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  
Senior Regulatory Affairs Specialist  
Phone: (763) 526-9172  
Fax: (763) 367-8147  
Email: mary.e.donlin@medtronic.com

### 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 Cardioblade® 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.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

FEB 26 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: Cardioblade 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.

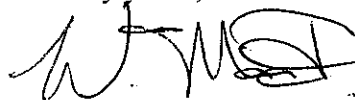
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



To 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    
(Part 21 CFR 801 Subpart D)

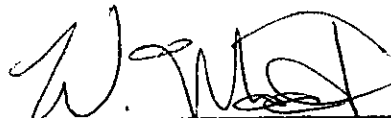
OR

Over-The-Counter-Use \_\_\_\_\_  
(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