Exhibit I

510(k) Summary

Submitter:	Medtronic, EP Systems Inc. CRM East Facility 7000 Central Avenue Fridley, MN 55432
Contact Person:	Mac McKeen, RAC Principal Regulatory Affairs Specialist Phone: (763) 514-3687 Fax: (763) 514-6424 Cell: (651) 270-4282 Email: mac.mckeen@medtronic.com
Date Prepared:	September 17, 2003
Trade Name:	EncirclrTM AL
Classification Name and Number:	21 CFR 870.1220
Product 1642:	DRF
Predicate Device Name and 510(k) Number	StableMapr K981642 Cleared August 5, 1998
Device Description:	DEVICE DESCRIPTION The device consists of a control handle and a closed lumen 7 French catheter shaft that transitions to a 5 French distal tip section. The distal tip section has an adjustable loop with 10 evenly spaced radiopaque active electrodes that are .75 to 1.3 mm in width, and a non-active 5 French distal tip. The catheter contains two control wires, insulated recording wires, and a nickel/titanium forming wire which has memory and elasticity that allows for adjustability of the loop. The control handle enables the user to steer the device, and adjust the diameter of the loop at the distal end of the catheter in order to fit various ostial anatomy. These catheters are available in four models (1045AL1, 1045AL2, 1060AL1, 1060AL2) with a usable length of 110 cm measuring from the strain relief to the center of the distal loop. They have curve reaches that

	range from 45 to 60 mm, and adjustable loop diameters that range from 14 to 28 mm (AL1's range is14-22mm and AL2's range is 18-28mm). The catheter connects to a cable that serves as the interface between the catheter and a standard EP recording system using a Medtronic 10-pin connector cable. The catheter is supplied sterile and is intended for single-use.
Indication for Use:	The Encirclr AL catheter is intended for electrophysiologic mapping, recording intracardiac electrograms, and temporary pacing in the atria of the heart.
Statement of Technological Comparison	Representative samples of the device underwent electrical and mechanical testing to demonstrate comparable functional and performance characteristics to the predicate device. The patient contact materials of the Encirclr AL are identical to those used in other legally marketed predicate devices from Medtronic that have undergone appropriate biocompatibility testing. Therefore biocompatibility testing of the Encirclr has been fulfilled by analogy to those catheters.
Conclusion: (statement of equivalence)	The Encirclr AL is substantially equivalent to the StableMapr EP catheter. This conclusion is based upon the fact that this device is substantially equivalent to the predicate device in terms of functional design, materials, intended use, and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2004

Medtronic, Inc.
c/o Mr. Mac McKeen, RAC
Principal Regulatory Affairs Specialist
7000 Central Avenue NE
Minneapolis, MN 55432

Re: K033050
Trade Name: Encirclr™ AL Adjustable Loop Mapping Catheter
Regulation Number: 21 CFR 870 1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: II (two)
Product Code: DRF
Dated: January 14, 2004
Received: January 15, 2004

Dear Mr. McKeen:

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 (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/dsma/dsmamain.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_ K033050

Device Name: EncirclrTM AL Adjustable Loop Mapping Catheter

Models 1045AL1, 1045AL2, 1060AL1, 1060AL2

Indications For Use:

The Encirclr AL Adjustable Loop Mapping Catheter is intended for electrophysiologic mapping, recording intracardiac electrograms, and temporary pacing in the atria of the heart.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochniel

Division Sign-Off)
Division of Cardiovascular Devices

10(k) Number K033050