510 (K) SUMMARY of Safety and Effectiveness

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

SEP - 2 2004

I. Applicant Information:

Date Prepared:	July 29, 2004
Submitter:	Medtronic, Inc.
Address:	710 Medtronic Parkway, NE Minneapolis, MN 55432-5604
Establishment Registration No.	2135394
Contact Person:	David D. Cox Principle Regulatory Affairs Specialist
Telephone Number:	(763) 391-9251
Fax Number:	(763) 391-9279

II. Device Information:

Trade Name:	Detect™ Mapping and Pacing Tool
Common Name:	Detect™ Electrode Probe
Classification Name:	Electrode, Pacemaker, Temporary
Classification:	Class II, 21 CFR 870.3680
Product Code:	LDF
Predicate Device:	Streamline™ 6494 Unipolar Temporary Myocardial Pacing Wire 510(k) No. K012459, Reg. No. 870.3680; Product Code: LDF

Device Intended Use: The Model 6494 Unipolar Temporary Myocardial Pacing Wire is intended for temporary atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and is intended for SINGLE USE ONLY.

Device Description: The Medtronic® Detect™ Temporary Pacing and Mapping Electrode Probe consists of a handle, a malleable stainless steel shaft with a flouropolymer sheath ending in a textured ball tip electrode, and a cable for connection to diagnostic device. Sterile, Nonpyrogenic, Disposable, Single use only.

The Grounding Electrode consists of a needle and a cable for connection to a diagnostic device. Sterile, Nonpyrogenic, Disposable, Single use only.

The Detect™ Electrode Probe is compatible with the Medtronic External Temporary Pacemaker (Model 5388), and the Medtronic® Programmer/ Analyzer (Model 2090/2290).

Intended Use: The DETECT™ Surgical Pacing and Mapping Tool is a handheld, single use device designed to provide temporary cardiac pacing or monitoring.

III. SUBSTANTIAL EQUIVALENCE TESTING SUMMARY

The DETECT™ Mapping and Pacing Tool and the Grounding Needle Electrode have been tested and are considered safe and effective per the "Electrode Recording Catheter Preliminary guidance", Mark Massi, Pacing and Electrophysiology Device Branch, Division of Cardiovascular, Respiratory and Neurological Devices, Office of Device Evaluation FDA, CDRH, 1995.

The DETECT™ Mapping and Pacing Tool and the Grounding Needle Electrode have been tested and are considered safe and effective per "Standard for Medical Equipment; Part 1: General requirements, IEC 60601-1; IEC 60601-27

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medtronic, Inc
c/o David D. Cox, Ph.D.
Principle Regulatory Affairs Specialist
Cardiac Surgery Technologies
710 Medtronic Parkway, NE
Minneapolis, MN 55432-5604

Re: K040812
Trade Name: Detect™ Mapping and Pacing Tool
Regulation Number: 21 CFR 870.3680
Regulation Name: Cardiovascular Permanent or Temporary Pacemaker Electrode
Regulatory Class: II (two)
Product Code: LDF
Dated: July 30, 2004
Received: August 02, 2004

Dear Dr. Cox:

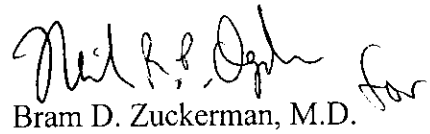
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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): **K040812**

Device Name: **Detect™ Surgical Pacing and Mapping Tool, Model 10650**

Indications for Use:

The DETECT™ Surgical Pacing and Mapping Tool is a handheld, single use device designed to provide temporary cardiac pacing or monitoring.

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 THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for bdz

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040812