K022238

OCT 0 9 2002

510(k) SUMMARY

Date Prepared:	July 10, 2002
	Medtronic, Inc. 7000 Central Ave. N.E. Minneapolis, MN 55432
Contact:	Mary Ellen Best Senior Product Regulation Manager Telephone: (763) 514-4846 Facsimile: (763) 514-6424 E-mail: mary.ellen.best@medtronic.com
Trade / Proprietary Name:	Medtronic Model 10626 Myocardial Implant Tool
Common Name:	Myocardial Pacing Lead (Accessory)
Device Classification:	I
Product Code:	**DWS**

Device Description

The implant tool consists of a handle, malleable shaft and lead hub fixation assembly (tongs) which grab and release a Model 5071 lead when the spring-loaded button actuator is depressed and released. The handle assembly includes a rotable, thumbwheel. Rotation of this thumbwheel in a clockwise direction results in equivalent rotation of a lead hub fixation assembly located at the distal end of the tool. Depression of the actuator allows fixation to the Model 5071 lead and also activates the fixation release upon completion of implant. Release of the actuator activates the fixation of the tool to the Model 5071 lead.

Indications for Use

The Myocardial Implant Tool is a single use device, intended to facilitate myocardial pacing lead placement. It is designed to assist in the placement and manipulation of the Model 5071 myocardial pacing lead.

Substantially Equivalent Device

The Model 10626 Myocardial Lead Implant Tool has the same intended use as the implant tool that is currently packaged with the Model 5071 lead. The technological differences between the Model 10626 and the predicate implant tool have been sufficiently evaluated to determine that these technological differences do not diminish the safety or effectiveness of the device.

Summary of Studies

Medtronic has thoroughly evaluated the Myocardial Lead Implant Tool, Model 10626 through in vitro testing to assure suitability for its intended used. Testing was performed on tools built according to a documented process and subjected to environmental conditioning.

In vitro testing includes:
- Visual Examination
- Grabber Insertion/Removal
- Grabber Rotation
- Lead Fixation / Removal
- Shaft Rotation
- Shaft Flexibility
- Mechanical testing of tong retention, actuator button, and retainer retention

The Model 10626 meets the requirements of the product specification as defined by Medtronic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

Medtronic, Inc.
c/o Mary Ellen Best
Principle Regulatory Affairs Specialist
Cardiac Rhythm Management
7000 Central Avenue NE
Minneapolis, MN 55432

Re: K022238
Trade Name: Model 10626 Myocardial Lead Implant Tool
Regulation Number: 21 CFR 870.4500
Regulation Name: Cardiovascular Surgical Instrument
Regulatory Class: Class I (one)
Product Code: DWS
Dated: July 10, 2002
Received: July 11, 2002

Dear Ms. Best:

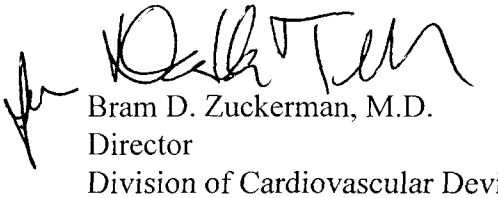
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4646. 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,



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):	N/A
Device Name:	Model 10626 Myocardial Lead Implant Tool
Indications For Use:	The Medtronic Model 10626 Myocardial Implant Tool is used to facilitate myocardial pacing lead placement. It is designed to assist in the placement and manipulation of the Model 5071 myocardial pacing lead.
Contraindications:	None

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022238

(Optional Format 1-2-96)

Medtronic