ATTACHMENT D
510(K) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Submitter

Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, MN 55432

Contact: Tina Benoit, Associate Product Regulation Manager
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Date Prepared: July 31, 2001

Name of Device

Trade Name: Temporary Pacemaker Electrode, 74 LDF

Common Name: Temporary Pacing Lead

Classification: Class II

Predicate Devices

The predicate device for the Model 6500 Unipolar Temporary Myocardial Pacing Lead is the currently market released Model 6500 Unipolar Temporary Myocardial Pacing Lead.

Device Description

The Model 6500 Unipolar Temporary Myocardial Pacing Lead consists of an electrode and an insulated multi-filament conductor which are crimped together. A blue monofilament proximally coiled for fixation of the lead is attached to the electrode and terminates distally in an atraumatic myocardial curved needle. A blue monofilament coil provides fixation while the lead is implanted in myocardial tissue. An atraumatic chest needle at the proximal end of the conductor wire permits exiting the pacing lead through the chest wall. To remove the pacing lead, gentle traction should be applied. No part of the lead remains in the body, except the silicone rubber disc in case of atrial application.

Packaging

The sterile packaging for the Model 6500 Unipolar Temporary Myocardial Pacing Lead consists of a double pouch configuration. The inner pouch (or package liner) and outer pouch materials are transparent Tyvek - polyester/polyethylene laminate. The pouches are heat-sealed.

Intended Use

The is designed for temporary atrial and ventricular pacing and sensing for a contemplated implant duration of 7 day or less. The device is supplied sterile and intended for single use only.

Technological Characteristics

The technology used with the Model 6500 Unipolar Temporary Myocardial Pacing Lead is the same technological characteristics as the predicate device.

Summary of Studies

Medtronic, Inc. performed system compatibility testing to support that the Model 6500 Unipolar Temporary Myocardial Pacing Lead is equivalent to the predicate device. Device testing included:

- Environmental Conditioning

- Visual Verification
- Dimensional Testing
- Electrical Testing
- Mechanical Testing

All system compatibility tests performed have demonstrated that the modified Model 6500 heartwire meets the specified requirements.

Sterilization Validation

The Model 6500 Unipolar Temporary Myocardial Pacing Lead is sterilized using a 100% Ethylene Oxide (ETO) sterilization process. Processes appropriate for sterilizing the devices were validated.

Conclusion

Through data and information presented, numerous similarities support a determination of substantial equivalence and show the device modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device. Market clearance of the Model 6500 Unipolar Temporary Myocardial Pacing Lead is supported through this Special 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2001

Ms. Tina L. Benoit
Medtronic, Inc.
Cardiac Rhythm Management
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K012452
Trade Name: Model 6500 Unipolar Temporary Myocardial Pacing Lead
Regulation Number: 21 CFR 870.3680
Regulatory Class: Class II (two)
Product Code: 74 LDF
Dated: July 31, 2001
Received: August 1, 2001

Dear Ms. Benoit:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): ~~N/A~~ K012452

Device Name: Medtronic® Model 6500 Unipolar Temporary Myocardial Pacing Lead

Indications For Use: The **Model 6500 Unipolar Temporary Myocardial Pacing Lead** is designed for temporary atrial and ventricular pacing and sensing for a contemplated implant duration of 7 days or less. The device is supplied sterile and intended for single use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012452