510(k) Summary

1. SUBMITTER'S NAME & ADDRESS	Susan Noddin, Product Regulation Manager Medtronic, Inc. 7000 Central Avenue NE Minneapolis, MN 55432 Phone: (612) 514-6191 Fax: (612) 514-6424
2. TRADE NAME: Common Name: Classification Name:	Bipolar transvenous temporary pacing lead, Model 6416 Temporary Pacing Lead Temporary Pacemaker Electrode
Classification	This device has been classified by the Circulatory Systems Device Panel into Class II, (21 CFR 870.3680(a)).
3. SUBSTANTIALLY EQUIVALENT DEVICE(S)	Temporary Transvenous Pacing Lead, Medtronic Model 6704, marketed via K772103, K790261 Medtronic Vector X Guiding Catheter, marketed via K950179
4. DEVICE DESCRIPTION	The Model 6416 lead consists of a small distal active fixation helix, tip and ring electrodes, an insulated coaxial conductor, and two staggered pin, low-profile bifurcation connectors. The Model 6416 system also includes a guiding catheter which is used for percutaneous lead introduction and placement in the heart. After implantation of the lead, the catheter is removed, and the lead's connectors are attached to an external pulse generator for a contemplated implant duration of up to 7 days. After completion of therapy, the lead is removed by counter-rotation and gentle traction. No part of the device remains in the body.
5. INDICATIONS FOR USE	The Medtronic Model 6416 Temporary, Transvenous Pacing Lead System features an active fixation, bipolar lead and a soft-tipped lubricated guide catheter. The system is designed for temporary intracardiac pacing and/or EGM recording. The system is disposable, for temporary single patient use with a contemplated implant duration of 7 days or less. The lead and accessories are supplied sterile. The lead is introduced transvenously using the guide catheter. Once within the appropriate chamber, the helical tip electrode of the lead is actively fixed into the endocardium. After lead placement, the guide catheter is removed by sliding it over the lead's bifurcated connector.
6. TECHNOLOGICAL CHARACTERISTIC COMPARISONS	The bipolar transvenous temporary pacing lead system, Model 6416 is substantially equivalent to the following products: Bipolar temporary tranvenous pacing lead, Medtronic Temptron Model 6704 (K772103, K790261). Medtronic Vector X Guiding Catheter (K950179). The table that follows contains a comparison of the similarities and differences of the Model 6416 to the predicate devices to which it is substantially equivalent. Similarities between the Model 6416 and the comparison devices are noted.

Feature	Model 6416 Lead	Model 6704 Lead
Lead Type	Temporary, single-use	Same
Intended use (including anatomical site)	Transvenous atrial and ventricular bipolar pacing	Transvenous ventricular bipolar pacing
Lead Introduction Method	Percutaneous, assisted by disposable guiding catheter	Percutaneous, assisted by disposable introducer
(Minimum) Device Compatability	Medtronic external cardiac stimulators and cable accessories	Same
Distal configuration	Straight with fixation helix	Straight, no fixation
Lead Body	3.5 French coaxial wire 16-wire braid with 3 inner conductors	4 French coaxial wire 16-wire braid with 3 inner conductors
Ring and Tip Electrodes	316L stainless steel	316 / 304 stainless steel
Electrode surface area	Tip: 4.3 mm^2 Ring: 17 mm^2	Tip: 12 $\pm$ 1 mm^2 Ring: 20 $\pm$ 2 mm^2
Electrode ring:tip ratio	4:1	1.6:1
Electrode spacing	1 centimeter	Same
Outer Insulation material	Polyethylene	Same
Inner insulation material	FEP	Nylon
Lead length	100, 140, & 200 cm	110 cm
Connector type	Staggered pin, low profile bifurcation	In-line connector with separate bifurcation assembly
Connector polarity markings	Long (-) & short (+) wires	Molded (+) and (-) on connectors
Included accessories	Catheter, hemostasis valve/ cap, torque tool	Bifurcation assy/ introducer set
Sterilization Method	100% EtO	Same
Packaging	5 sterile packages per carton	Same
Feature	**Model 6416 Guiding Catheter**	**Vector X Guiding Catheter**
Guiding Catheter	Radiopaque marker bands	No marker bands
All other features	Same	Same
7. SUMMARY OF STUDIES	Medtronic, Inc. performed device integrity testing to support the Model 6416 is substantially equivalent to the predicate devices. Device integrity testing included: Visual verification — Dimensional verification Electrical verification — Pull strength verification Flex life verification All test results for the device met specified requirements.	
8. CONCLUSION (STATEMENT OF EQUIVALENCE)	Through the data and information provided in this submission, numerous similarities support a substantial equivalence determination, and, therefore, clearance of the 510(k) notification for the Model 6416.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 1998

Ms. Susan Noddin
Product Regulation Manager
Medtronic, Inc.
7000 Central Avenue, N.E.
Minneapolis, MN 55432-3576

Re: K973360
Trade Name: Medtronic Model 6416 Transvenous Bipolar Temporary Pacing Lead System
Regulatory Class: II
Product Code: LDF
Dated: March 19, 1998
Received: March 20, 1998

Dear Ms. Noddin:

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) 594-4618. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

The Medtronic Model 6416 Temporary, Transvenous Pacing Lead System features an active fixation, bipolar lead and a soft-tipped lubricated guide catheter. The system is designed for temporary intracardiac pacing and/or EGM recording.

The system is disposable, for temporary single patient use with a contemplated implant duration of 7 days or less. The lead and accessories are supplied sterile.

The lead is introduced transvenously using the guide catheter. Once within the appropriate chamber, the helical tip electrode of the lead is actively fixed into the endocardium. After lead placement, the guide catheter is removed by sliding it over the lead's bifurcated connector.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K973360

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)