K982220

510(k) Summary

1. SUBMITTER'S NAME & ADDRESS	Brian Edwards, Product Regulation Manager Medtronic, Inc. 7000 Central Avenue NE Minneapolis, MN 55432 Phone: (612) 514-3962 Fax: (612) 514-6424
2. TRADE NAME: Common Name: Classification Name:	Bipolar lead adaptor kit, Model 2872 Pacemaker Lead Adaptor Adaptor, Lead, Pacemaker 74DTD
Classification	This device has been classified by the Circulatory Systems Device Panel into Class III, (21 CFR 870.3680(a)).
3. SUBSTANTIALLY EQUIVALENT DEVICE(S)	Medtronic Model 5866-38M Lead Adaptor Kit, marketed via K911302
4. DEVICE DESCRIPTION	The Model 2872 lead adaptor consists of stainless steel connectors, MP35N conductor coils, and silicone rubber insulation. Also packaged in the kit are wrench / setscrew assemblies, and a tube of medical grade adhesive.
5. INDICATIONS FOR USE	The Model 2872 Lead Adaptor Kit is designed to connect two pacing leads with bipolar connectors (IS-1 BI) to a pulse generator featuring a bipolar connector block which meets the IS-1 BI standard.
6. TECHNOLOGICAL CHARACTERISTIC COMPARISONS	The Model 2872 Bipolar Lead Adaptor Kit is substantially equivalent to the following product: Medtronic Model 5866-38M Lead Adaptor Kit (K911302) The table that follows contains a comparison of the similarities and differences of the Model 2872 to the predicate devices to which it is substantially equivalent. Similarities between the Model 2872 and the comparison device are noted.

Feature	**Model 2872 Lead Adaptor**	**Model 5866-38M Lead Adaptor (K911302)**
Lead Adaptor Type	Bipolar	Same
Intended use (including anatomical site)	Implanted in a pacemaker pocket; intended to connect two pacing leads with bipolar connectors (IS-1 BI)* to a pulse generator featuring a bipolar connector block which meets the IS-1 BI* standard	Implanted in a pacemaker pocket; intended to connect two pacing leads with unipolar connectors (IS-1UNI)* to a pulse generator featuring a bipolar connector block which meets the (IS-1 BI)* standard.
Application	Permanent Implantable bipolar lead adaptor kit	Same

25

(Minimum) Device Compatability	Medtronic pulse generators featuring a bipolar connector block which meets the IS-1BI standard	
Conductor Material	MP35N conductor coils	
Outer Insulation material	Silicone rubber	
Connector Material	Stainless Steel	
Lead adaptor length	130 mm	139.7 mm
Lead adaptor body diameter	2.31mm	
Resistance: Tip / tip connector block Ring / ring connector block	 maximum 20Ω maximum 20Ω	 maximum 15Ω maximum 15Ω
Connector type	IS-1BI	
Included accessories	Wrench and setscrew assemblies, tube of medical adhesive	
Sterilization Method	100% EtO	
Packaging materials	Spunbonded olefin tray and pouch	
7. SUMMARY OF STUDIES	Medtronic, Inc. performed device integrity testing to support the Model 2872 is substantially equivalent to the predicate device. 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 2872.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 1998

Mr. Brian J. Edwards, M.S.
Product Regulation Manager
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 5543 2-3576

Re: K982220
Trade Name: Model 2872 Bipolar Lead Adaptor Kit
Regulatory Class: III
Product Code: DTD
Dated: October 1, 1998
Received: October 2, 1998

Dear Mr. Edwards:

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

1

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) 594-4586. 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 Model 2872 Lead Adaptor Kit is designed to connect two pacing leads with bipolar connectors (IS-1 BI)* to a pulse generator featuring a bipolar connector block which meets the IS-1 BI* standard.

*IS-1 refers to an International Connector Standard (ISO 5841-3; 1992) whereby pulse generators and leads so designated are assured of a basic mechanical fit.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982220

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)