K132008

2.0 510(k) Summary

Date Prepared: June 28, 2013

Submitter:

Medtronic, Inc.
Medtronic Cardiac Rhythm Disease Management
8200 Coral Sea Street N.E.
Mounds View, MN 55112
Establishment Registration Number: 2182208

JUL 30 2013

Contact Person:

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Device Name and Classification

Trade Name:
6981M Lead Extender Kit
6984M Lead Extender Kit
5866-24M Lead Adaptor Kit
5866-38M Lead Adaptor Kit
5866-40M Lead Adaptor Kit

	6986M Lead Extender Kit
Common Name:	Pacemaker Lead Adaptor
Regulation Number:	21 CFR 870.3620
Product Code:	DTD
Classification:	Class II
Classification Panel:	Cardiovascular
Special Controls:	"Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510 (k) Submissions"

Predicate Devices

K911827	6981M Lead Extender Kit
K915724	6984M Lead Extender Kit
K911302	5866-24M Lead Adaptor Kit
	5866-38M Lead Adaptor Kit
	5866-40M Lead Adaptor Kit
	6986M Lead Extender Kit

Device Description/Indications for Use

Model	Device Description/Indications for Use
6981M Lead Extender Kit	The 6981M Lead extender kit is designed to extend, by 37 cm (14.6 in.), the length of a pacing lead system with a unipolar connector that meets the (IS-1 UNI) standard.
6984M Lead Extender Kit	The 6984M Lead Extender Kit is designed to extend, by 37 cm (14.6 in.), the length of a pacing lead system with a bipolar connector that meets the (IS-1 BI) standard.
5866-24M Lead Adaptor Kit	The 5866-24M Lead adaptor kit is designed to connect a Medtronic pacing lead with a bipolar connector (5mm bifurcated) to a pulse generator featuring a bipolar connector block which meets the (IS-1 BI) standard.
5866-38M Lead Adaptor Kit	The 5866-38M Lead adaptor kit is designed to connect two pacing leads with unipolar connectors (IS-1 UNI) to a pulse generator featuring a bipolar connector block which meets the (IS-1 BI) standard.
5866-40M Lead Adaptor Kit	The Model 5866-40M Lead Adaptor Kit is designed to connect a Medtronic pacing lead with a bipolar connector (3.2 mm low-profile) to a pulse generator featuring a bipolar connector block which meets the (IS-1 BI) standard and has a short-pin cavity and no sealing rings.

6986M Lead Extender Kit	The 6986M Lead adaptor/Extender kit is designed to extend, by 37 cm (14.6 in.), the length of a 3.2 mm low-profile connector pacing lead system and connect to a pulse generator featuring a bipolar connector block that meets the (IS-1 BI) standard.

Comparison to Predicate Devices

When compared to the predicate devices (K911827, K915724 & K911302), the Medtronic Lead Adaptor Kit and Lead Extender Kit models presented in this submission have the following similarities:

- Intended use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Biological safety
- Packaging materials
- Sterilization and sterility assurance level
- Shelf life

Performance Testing

The assessment of the material change being made to the Lead Adaptor Kit and Lead Extender Kit products was carried out using Design Controls compliant to 21 CFR 820.30. The safety and effectiveness of the product has been ensured through performance testing. Verifications included:

Performance Testing

- Dielectric Withstanding Voltage Test
- Saline Soak / Electrical Impedance
- Fluid Leakage
- Composite Tensile Integrity
- Composite Tensile Strength
- Lead Body Reverse Bend

Biocompatibility Assessment

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity

- Systemic Toxicity
- Genotoxicity
- Implantation

Sterilization Testing

- Residual Testing

Conclusion

Medtronic has demonstrated that the modifications made to the Lead Adaptor Kit and Lead Extender Kit products described in this submission result in a substantially equivalent device because the fundamental scientific principle, operating principle, design features and intended use are unchanged from the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 30, 2013

Medtronic, Inc.
Michele Machacek
8200 Coral Sea Street NE
Mounds View, MN 55112 US

Re: K132008
Trade/Device Name: 6981M, 6984M, 6986M Lead Extender Kits
5866-24M, 5866-38M, 5866-40M Lead Adaptors
Regulation Number: 21 CFR 870.3620
Regulation Name: Pacemaker Lead Adaptor
Regulatory Class: Class II
Product Code: DTD
Dated: June 28, 2013
Received: July 1, 2013

Dear Michele Machacek:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K132008

Device Name:

6981M Lead Extender Kit

Indications for Use:
The 6981M Lead extender kit is designed to extend, by 37 cm (14.6 in.), the length of a pacing lead system with a unipolar connector that meets the (IS-1 UNI) standard.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.07.30
10:24:22 -04'00'

Statement of Indications for Use

510(k) Number (if known): K132008

Device Name:

6984M Lead Extender Kit

Indications for Use:
The 6984M Lead Extender Kit is designed to extend, by 37 cm (14.6 in.), the length of a pacing lead system with a bipolar connector that meets the (IS-1 BI) standard.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Statement of Indications for Use

510(k) Number (if known): K132008

Device Name:

5866-24M Lead Adaptor Kit

Indications for Use:
The 5866-24M Lead adaptor kit is designed to connect a Medtronic pacing lead with a bipolar connector (5mm bifurcated) to a pulse generator featuring a bipolar connector block which meets the (IS-1 BI) standard.

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 LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Statement of Indications for Use

510(k) Number (if known): K132008

Device Name:

5866-38M Lead Adaptor Kit

Indications for Use:
The 5866-38M Lead adaptor kit is designed to connect two pacing leads with unipolar connectors (IS-1 UNI) to a pulse generator featuring a bipolar connector block which meets the (IS-1 BI) standard.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Statement of Indications for Use

510(k) Number (if known): K132008

Device Name:

5866-40M Lead Adaptor Kit

Indications for Use:
The Model 5866-40M Lead Adaptor Kit is designed to connect a Medtronic pacing lead with a bipolar connector (3.2 mm low-profile) to a pulse generator featuring a bipolar connector block which meets the (IS-1 BI) standard and has a short-pin cavity and no sealing rings.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Statement of Indications for Use

510(k) Number (if known): K132008

Device Name:

6986M Lead Extender Kit

Indications for Use:
The 6986M Lead adaptor/Extender kit is designed to extend, by 37 cm (14.6 in.), the length of a 3.2 mm low-profile connector pacing lead system and connect to a pulse generator featuring a bipolar connector block that meets the (IS-1 BI) standard.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)