FEB 14 2014

510(k) Summary

Date Prepared:	15 August 2013
Submitter:	Medtronic, Inc. Cardiac Rhythm Disease Management 8200 Coral Sea Street NE Mounds View, MN 55112
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Proprietary Name:	Reveal LINQ™ Insertable Cardiac Monitor, Model LNQ11 Reveal Patient Assistant 9538
Common Name:	Arrhythmia detector and alarm
Device Classification	Class II, 21 CFR 870.1025, Arrhythmia detector and alarm
Product Code:	DSI

Summary of Substantial Equivalence

The intended use, design, materials and performance of the Reveal LINQ ICM (Model LNQ11) and Reveal Patient Assistant (Model 9538) are substantially equivalent to the following predicate devices:

- The Reveal XT (Model 9529) and Reveal DX (Model 9528) were initially cleared via separate 510(k) applications, reference numbers K071641, K071655 on November 21, 2007. The Reveal XT (Model 9529) and Reveal DX (Model 9528) most recent modifications submission were cleared via K103764 on May 4, 2011.
- Instromedix King of Hearts Express AF Recorder - K020825, Cleared April 5,2002

Device Description

The Reveal LINQ Model LNQ11 Insertable Cardiac Monitors (ICM) is designed to automatically record the occurrence of arrhythmias in a patient. Arrhythmia may be classified as atrial tachyarrhythmia/atrial fibrillation (AT/AF), bradyarrhythmia, pause, or (fast) ventricular tachyarrhythmia. The Reveal LINQ ICM provides storage of ECG and Marker Channel during patient-activated and automatically-detected (auto-activated) events. Auto activation may help to detect abnormal heart rhythms in patients who may not activate/trigger the ICM.

The Reveal LINQ model LNQ11 is a small, leadless device that is typically implanted under the skin, in the chest. Two electrodes on the body of the device continuously monitor the patient's subcutaneous ECG.

A set of tools are provided with the Reveal LINQ ICM to create the small incision in the skin and to easily form a tight pocket and insert the ICM into the shallow subcutaneous pocket. There are two implant tools: the Incision Tool, used to make a small incision through the patient's skin; and the Insertion Tool, used to insert the device through the incision and into the patient's body at the desired location.

The Reveal Patient Assistant Model 9538 is a hand-held, battery-operated telemetry devices The Patient Assistant activates the data management features in the Reveal LINQ ICM to initiate recording of cardiac event data in the implanted device memory.

Indications for Use

There are no changes to the Indications for Use. The Indications for Use are provided below:

The Reveal LINQ Insertable Cardiac Monitors is an implantable patient-activated and automatically-activated monitoring system that record subcutaneous ECG and are indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain, that may suggest a cardiac arrhythmia.

The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management features in the Reveal LINQ ICM to initiate recording of cardiac event data in the implanted device memory.

Technological Characteristics

Intended use, design, materials, performance and technological characteristics are substantially equivalent to the predicate devices referenced.

Summary of Testing

Device system verification and validation testing was performed to demonstrate the Reveal LINQ Model LNQ11 Insertable Cardiac Monitor and its accessories meet established performance criteria to support equivalency to the reference predicate devices.

In addition the following testing was completed Reveal LINQ ICM Model LNQ11:

Performance Testing – Bench

- Electromagnetic compatibility (EMC)
- Electrical safety
- Firmware and Hardware verification
- Mechanical Verification
- Implant Tools Verification

- Packaging Design Verification
- Sterilization
- Biocompatibility
- MRI compatibility
- Sensing and Detection performance validation
- System Validation
- Only the labeling changed to support Reveal LINQ ICM for the Reveal Patient Assistant Model 9538, therefore no performance testing was completed on the 9538 Patient Assistant.

Performance Testing – Animal

- Reveal LINQ GLP Study

Performance Testing – Clinical

The following table summarizes the clinical studies that support the incremental features and labeling of LINQ:

Table 1: Study Summaries

Study Name / Number	Design	Primary Objectives	Results
XPECT Trial	**Type:** Validation **Follow-up:** 46 hours **Sample:** N = 247 **Device:** Reveal XT	To assess whether the AF detection algorithm reliably detected the presence or absence of AF. The XPECT trial utilized a specialized Holter to record the accuracy of the AF algorithm.	The sensitivity, specificity, positive predictive value, and negative predictive value for identifying patients with any AF were 96.1%, 85.4%, 79.3%, and 97.4%, respectively. Overall accuracy reported for detecting AF was 98.5% for the Reveal XT ICM.[12]
AIM Study	**Type:** Prospective, multicenter, feasibility Follow-Up: Acute Sample: N= 41 Device: Reveal LINQ Profile Force Probe	To characterize the insertion force based on various disease states and body types.	The insertion force of a medical device implant is higher in males than females and may exceed the limit of 5 pounds of force. This data contributed to development of Insertion Tool.
MapReveal	**Type:** Prospective, multicenter, feasibility **Follow-up:** 24 hours to > 1 month **Sample:** N = 42 **Device:** Reveal DX/XT	To assess the signal amplitude at the recommended location of V_2V_3, 45 degrees. This study was designed to collect 24 hour ambulatory surface ECG mapping data and acute subcutaneous ECG data with electrode spacing shorter than that of the Reveal DX/XT devices.	The recommended location offered acceptable R-wave amplitude when selected without mapping.
Subcutaneous Implant Migration (SubQ-IM)	**Type:** Prospective, multicenter, randomized feasibility **Follow-up:** 12 weeks **Sample:** N= 40 healthy volunteers (1 or 2 nonfunctional device prototypes)	To observe and quantify prototype migration, or lack thereof, as well as the force of device insertion.	Using fluoroscopy imaging, results of this study indicated that no significant migration occurred for a device of identical weight and shape of the Reveal LINQ device. Additionally, data regarding the force measurements contributed to the development of the Insertion Tool and Subcutaneous ECG measurements contributed to the

Study Name / Number	Design	Primary Objectives	Results
	Device: Reveal LINQ Nonfunctional Prototype		recommended "Good" and "Best" Locations.

Performance Testing – Human Factors

- Formative and Validation Testing

The following standards were used for bench testing; Sterilization testing; Software testing; Electromagnetic Compatibility and Electrical Safety testing; and Biocompatibility testing:

	Standard
1	AAMI / ANSI / IEC 62366:2007/2008 Medical devices - Application of usability engineering to medical devices
2	ISO 10993-1:2010 (Forth Edition) Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
3	ISO 10993-7:2008 (Second Edition) Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
4	EN 45502-1:2003 Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
5	ISO 11135-1:2007 (First Edition)Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
6	EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
7	ISO 14971: 2007 (Second Edition) Medical devices - Applications of risk management to medical devices
8	IEC EN 62304: 2006/AC: 2008 Medical device software - Software life-cycle processes
9	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices.
10	IEC 60068-2-27:2008 Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock
11	ISO 14708-1:2000 Implants for surgery -- Active implantable medical devices -- Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
12	ISO/TS 10974:2012 Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

The results of the testing indicate that the Reveal LINQ ICM Model LNQ11, implant tools and Reveal Patient Assistant Model 9538 perform as intended and are safe and effective for their intended use.

Reveal Patient Assistant Model 9538 Performance Testing

Only the labeling changed for the Reveal Patient Assistant Model 9538, therefore no performance testing was completed on the 9538 Patient Assistant.

The results of the testing indicate that the Reveal LINQ Insertable Cardiac Monitor Model LNQ11, implant tools and Reveal Patient Assistant Model 9538 perform as intended and are safe for their intended use.

Conclusion

Medtronic has demonstrated that the Reveal LINQ device 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

February 14, 2014

Medtronic, Inc.
Eric Kalmes
Principal Regulatory Affairs Specialist
8200 Coral Sea Street, MVS11
Mounds View, MN 55112

Re: K132649
Trade/Device Name: Reveal LINQ Insertable Cardiac Monitor (ICM) model LNQ11, Reveal Patient Assistant Model 9538, and Implant Tools
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm
Regulatory Class: Class II
Product Code: DSI
Dated: February 10 2014
Received: February 11, 2014

Dear Mr. Eric Kalmes:

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

Indications For Use

510(k) Number (if known): _K132649_____

Device Name: Reveal LINQ™ Insertable Cardiac Monitor and Reveal XT Patient Assistant

Indications for Use: The Reveal LINQ Insertable Cardiac Monitor is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain that may suggest a cardiac arrhythmia.

The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management features in the Reveal LINQ ICM to initiate recording of cardiac event data in the implanted device memory.

Prescription Use X AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2014.02.14 07:23:10 -05'00'