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

May 26, 2016

Medtronic, Inc.
Dianna Johannson
Sr. Principal Regulatory Affairs Specialist
8200 Coral Sea St Nw
Mounds View, Minnesota 55112

Re: K160809
Trade/Device Name: Reveal LINQ Insertable Cardiac Monitor, Model LNQ11
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: DSI
Dated: April 26, 2016
Received: April 27, 2016

Dear Dianna Johannson:

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.

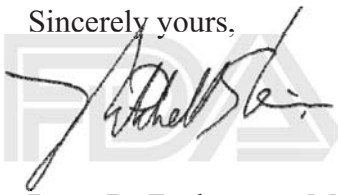
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Industry and Consumer Education 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 Industry and Consumer Education 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,



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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160809

Device Name
Reveal LINQ Insertable Cardiac Monitor (Model LNQ11)

Indications for Use *(Describe)*

The Reveal LINQ ICM is an insertable automatically-activated and patient-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 device has not been tested specifically for pediatric use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Medtronic
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510(k) Summary

Date Prepared:	18 March 2016
510(k) Owner / Address:	Medtronic, Inc. Cardiac Rhythm and Heart Failure 8200 Coral Sea Street Mounds View, MN 55112
Contact:	Dianna L. Johannson Sr. Pr. Regulatory Affairs Specialist
Telephone:	(763) 526-2376
Fax:	(651) 367-0603
E-mail:	dianna.johannson@medtronic.com
Trade / Proprietary Name:	Reveal® LINQ™ Insertable Cardiac Monitor, Model LNQ11
Common Name:	Insertable Cardiac Monitor
Classification / Classification Name:	Class II (special controls) Arrhythmia detector and alarm (21 CFR 870.1025)
Product Code:	DSI

Summary of Substantial Equivalence

The intended use, design, materials and performance of the Reveal LINQ ICM (Model LNQ11) in association with the Reveal LINQ Mobile Manager App (Model MSW002) and patient connector (Model 24965) (referred to as the Reveal LINQ Mobile Manager) are substantially equivalent to the following predicate device:

- Reveal LINQ ICM (Model LNQ11) cleared via K150614 on 06AUG2015.

Device Description

The Reveal® LINQ™ Insertable Cardiac Monitor (ICM) Model LNQ11 is designed to 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 implantable device that is typically implanted under the skin, in the chest. Two electrodes on the body of the implantable device continuously monitor the patient's subcutaneous ECG.

Medtronic Reveal LINQ (Model LNQ11) ICM

The Reveal LINQ ICM is a small, leadless implantable device that is implanted under the skin, in the chest. The implantable device uses two electrodes on its surface to monitor the patient's subcutaneous ECG continuously. The implantable device memory can store up to 27 min of ECG recordings from automatically detected arrhythmias and up to 30 min of ECG recordings from patient-activated episodes. The system provides 3 options for segmenting the patient-activated episode storage: up to four 7.5 min recordings, up to three 10 min recordings, or up to two 15 min recordings. Arrhythmia detection parameters are set to pending automatically, based on patient information entered on the programmer during pre-insertion implantable device setup: the patient's Date of Birth and the clinician's Reason for Monitoring the patient. Arrhythmia detection parameters can also be programmed manually by the clinician. The following table describes the Reveal LINQ ICM Model LNQ11 when used with the new Reveal LINQ Mobile Manager App Model MSW002 for iOS and patient connector as compared to the Reveal LINQ ICM Model LNQ11 when used with the existing Reveal LINQ Mobile Manager App Model MSW001 for Android and patient connector.

Parameter	Reveal LINQ ICM Model LNQ11 (with existing Reveal LINQ Mobile Manager App Model MSW001 for Android and patient connector Model 24965)	Reveal LINQ ICM Model LNQ11 (with new Reveal LINQ Mobile Manager App Model MSW002 for iOS and patient connector Model 24965)
Longevity	3 years	Same
Electrode Spacing (inside-to-inside)	37.7 mm	Same
Volume	1.2 cc	Same
Mass	2.4 g	Same
Episode Storage	57 min	Same
Patient Symptom Mark	Patient Assistant	Same
Cardiac Compass	Yes	Same
MRI Compatibility	MR Conditional	Same
Clinician Notification	Nightly Transmission / Notifications	Same
Bi-Directional Telemetry	B	Same
Detection Algorithms	Full View + P-wave presence filter	Same
CareLink	Yes	Same
Wireless Telemetry	1-Way, Transmit Only	Same
Patient's CareLink Clinic Name and ID	Yes	Same

The Reveal LINQ ICM Model LNQ11 with existing Reveal LINQ Mobile Manager App Model MSW001 and patient connector Model 24965 was initially cleared via a 510(k) application K150614 on 06AUG2015. This submission is to add an app (Model MSW002) to the Reveal LINQ Mobile Manager for use on iOS mobile devices. The Reveal LINQ Mobile Manager for iOS devices is comprised of the Reveal LINQ Mobile Manager App Model MSW002 installed on a clinician's off-the-shelf non-medical iOS mobile device and patient connector Model 24965 (also referred to as a telemetry head) used in conjunction with the CareLink Network. The Reveal LINQ ICM continues to have the same intended use when used with the Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965. The Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965 provide the essential capabilities for programming, interrogating and managing the Reveal LINQ ICM in a clinical or hospital environment.

The Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965 have no impact on the physical characteristics, materials, mechanical, electrical, hardware, components, firmware, operation, performance, and telemetry protocol of the Reveal LINQ ICM. There are no differences in the performance, features, materials, hardware, firmware, intended use or programmer-to- implantable device interface between the Reveal LINQ ICM used with the Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965 versus the existing Reveal LINQ Mobile Manager App Model MSW001 and patient connector Model 24965. The Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965 are capable of interrogating and programming the Reveal LINQ ICM like the existing Reveal LINQ Mobile Manager App Model MSW001 and patient connector Model 24965.

Indications for Use

There are no changes to the cleared indications for use for the Reveal LINQ ICM Model LNQ11 when used with the Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965 as compared to the Reveal LINQ ICM Model LNQ11 indications when used with the existing Reveal LINQ Mobile Manager App Model MSW001 and patient connector Model 24965.

The indication statement is as follows:

> The Reveal LINQ ICM is an insertable automatically-activated and patient-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 device has not been tested specifically for pediatric use.

Technological Characteristics

The Reveal LINQ ICM consists of three major subassemblies which include the hermetically enclosed battery, hermetically enclosed electronics module, and molded header assembly. The battery is a custom D-shaped cell based on LiCFx chemistry and supports a 12-month shelf life and 3-year usable capacity. The Electronics Module contains the hybrid comprised of a printed circuit board with surface mount components on one side and an over molded stack on the other side which contains analog, digital and memory IC's along with capacitor arrays. The molded Header Assembly contains a Titanium Nitride coated sensing electrode, an embedded miniature RF antenna, suture hole, and a mounting bracket.

The Reveal LINQ ICM will continue to use the same technology. It is designed to automatically record the occurrence of an arrhythmia in a patient, continuously senses the patient's subcutaneous ECG, and analyzes the timing of ventricular events to detect possible episodes of arrhythmia. The Reveal LINQ ICM has a small form factor, and uses Titanium, Parylene, Urethane, and Titanium Nitride coating on the sensing electrodes as body contacting materials.

The use of the Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965 to support the Reveal LINQ ICM does not alter the existing technology of the Reveal LINQ ICM. Additionally, from the system perspective, the Reveal LINQ Mobile Manager App still communicates via an RF head (the patient connector) which in turn communicates with the Reveal LINQ ICM to program diagnostic settings and to extract data from the implantable device for viewing on either the Reveal LINQ Mobile Manager App or the Medtronic CareLink Network. The patient connector utilizes the same telemetry protocol (Telemetry B) to communicate with the Reveal LINQ ICM; however, it utilizes Bluetooth Low Energy technology to communicate with the mobile device, and has rechargeable battery-powered operation. The Reveal LINQ Mobile Manager App utilizes existing infrastructure of the clinician's mobile device to run the programming application, facilitating portability and mobility, direct connectivity with CareLink via cellular and Wi-Fi, Bluetooth Low Energy connectivity to communicate with the patient connector, software updates via publicly accessible channels (i.e. Apple App Store), and a user interface with workflows, streaming ECG waveform and marker display.

Summary of Testing

Testing was performed to demonstrate equivalency of the Reveal LINQ Model LNQ11 Insertable Cardiac Monitor with Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965 to the Reveal LINQ ICM with the existing Reveal LINQ Mobile Manager App Model MSW001 and patient connector Model 24965. The Reveal LINQ ICM with Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965 were subjected to the same use scenarios during testing as the Reveal LINQ ICM with the existing Reveal LINQ Mobile Manager App Model MSW001 and patient connector Model 24965, thus supporting substantial equivalency. Testing included:

Reveal LINQ ICM Model LNQ11 Testing

System verification and system validation were completed with the Reveal LINQ Model LNQ11 Insertable Cardiac Monitor.

Reveal LINQ Mobile Manager App Model MSW002 Testing

Performance verification as well as software verification, system verification and system validation were completed for the Reveal LINQ Mobile Manager App Model MSW002.

Patient Connector Model 24965 Testing

Electromagnetic compatibility (EMC), RF compliance, and wireless coexistence testing were completed on and with the patient connector. Additionally, firmware verification, system verification and system validation were completed with the patient connector. Electrical safety, mechanical, packaging, biocompatibility and performance verification testing were performed on the patient connector as part of K150614 but did not warrant repeating given the scope of this submission, that the Model 24965 electrical and mechanical design is unchanged, and that the Model 24965 hardware / materials and packaging are unchanged. The patient connector is provided non-sterile.

The results of the testing indicate that the Reveal LINQ Insertable Cardiac Monitor Model LNQ11 with the Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965 perform as intended, and are safe for their intended use.

The FDA recognized standards that the Reveal LINQ Insertable Cardiac Monitor Model LNQ11, Reveal LINQ Mobile Manager App (Model MSW002), and patient connector (Model 24965) complies are identified in the following tables.

Standards Referenced for the Reveal LINQ ICM

Standard		
Standards Organization / Number	**Standards Title**	**Date / Version**
AAMI / ANSI / IEC 62366	Medical devices - Application of usability engineering to medical devices	2007
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2010 (Forth Edition)
ISO 10993-7	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	2008 (Second Edition)
ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2009
ISO 14971	Medical devices - Applications of risk management to medical devices	2007 (Second Edition)
IEC 62304	Medical device software - Software life-cycle processes	2006

Standards Referenced for the Reveal LINQ Mobile Manager App

Standard		
Standards Organization / Number	**Standards Title**	**Date / Version**
IEC 62304	Medical device software – Software life cycle processes	2006
AAMI/ANSI/ IEC 62366	Medical devices – Application of usability engineering to medical devices	2007/(R)2013
ISO 14971	Medical devices – Application of risk management to medical devices	2007
ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements	2012

Standards Referenced for the Patient Connector

Standard		
Standards Organization / Number	**Standards Title**	**Date / Version**
AAMI/ANSI/ ISO 10993-1	Biological evaluation of medical devices. Evaluation and testing	2009/(R)2013
IEC 60601-1-2	Medical electrical equipment - Part 1: General requirements for basic safety and essential Performance	2007
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential Performance	2010
IEC 62133	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.	2012
IEC 62304	Medical device software – Software life cycle processes	2006
AAMI/ANSI/ IEC 62366	Medical devices – Application of usability engineering to medical devices	2007/(R)2013
ISO 14971	Medical devices – Application of risk management to medical devices	2007 / 2012
ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements	2012

Conclusion

Medtronic has demonstrated that the Reveal LINQ ICM (Model LNQ11) with the Reveal LINQ Mobile Manager App Model MSW002 and patient connector Model 24965 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 Reveal LINQ ICM with the existing Reveal LINQ Mobile Manager App Model MSW001 and patient connector Model 24965, and it continues to be safe, effective, and performs as intended.