DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

February 23, 2017

Medtronic, Inc.
Syed Mohiuddin
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K162855
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: January 20, 2017
Received: January 23, 2017

Dear Syed Mohiuddin:

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,

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)*
K162855

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: October 11, 2016

Submitter: Medtronic, Inc.
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General Information

Trade Name: Reveal LINQ™ Insertable Cardiac Monitor (Model LNQ11)

Common Name: Insertable Cardiac Monitor

Regulation Number: CFR 870.1025

Product Code: DSI

Classification: Class II

Classification Panel: Cardiovascular

Special Controls: Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm

Predicate Devices: Reveal LINQ Insertable Cardiac Monitor (Model LNQ11) K160809

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 ICM 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.

Indications for Use

There are no changes to the Indications for Use as a result of this submission. The Indications for Use are provided below:

> 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.

When compared to the predicate device, the existing Reveal LINQ ICM (cleared by FDA under **K160809**), the Reveal LINQ ICM with modified firmware (subject of this submission) has the same:

- Intended use/indications for use
- Operating principle
- Design features

- Device functionality
- Biological safety
- Packaging materials
- Shelf life

When compared to the predicate device, the existing Reveal LINQ ICM (cleared by FDA under **K160809**), the Reveal LINQ ICM with modified firmware (the subject of this submission) differs as follows:

- The Reveal LINQ ICM with modified firmware includes minor changes to enhance its atrial and ventricular arrhythmia detection algorithms by adding three rules to reduce false positive detections listed below:
  - Atrial Algorithms – Adaptive P-sense rule
  - Dual Sense Brady rejection rule
  - Dual Sense Asystole rejection rule
- The Reveal LINQ ICM with modified firmware includes minor cumulative updates that are categorized as under:
  - Minor diagnostic updates
  - Minor telemetry updates
  - LINQ RRT update integration
  - Minor bug fixes

Substantial Equivalence

Technological differences between the subject and predicate devices have been evaluated through bench testing to provide evidence of safe and effective use. The Reveal LINQ ICM with modified firmware is substantially equivalent to the predicate device, the existing Reveal LINQ ICM (cleared by FDA under **K160809**) based on comparisons of device functionality, technological characteristics, and indications for use.

Summary of Testing

Firmware regression testing, design verification, system verification, and system design validation testing were performed to demonstrate that the subject device – the Reveal LINQ ICM with modified firmware, met established performance criteria to support equivalency to the referenced predicate device, the existing Reveal LINQ ICM (cleared by FDA under **K160809**).

- **Firmware regression testing:** This testing of unchanged firmware was performed to ensure that no unintended side effects were introduced.
- **Firmware design verification:** This testing was made up of two parts: verification of the individual design artifacts (firmware units) associated with the development and release of the firmware; and verification of the finished firmware product (implemented design) to confirm that it meets the associated input requirements.
- **System level testing:** This testing was performed on the subject device – the Reveal LINQ ICM with modified firmware, which included system verification testing and system validation testing. System design verification ensured that the proposed

modifications did not impact the existing system level design inputs. System design validation confirmed through a combination of test and analysis that the stakeholder needs and intended use continued to be met by the subject device. The validation for the changes to enhance the atrial and ventricular algorithms of the Reveal LINQ ICM firmware was based on the *ANSI/AAMI EC57:1998 standard for Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms.*

The following standards and guidance documents were used for development and testing of the subject device:

Standard Number	Standard Organization	Standard Title
14971:2012	ISO	Medical Devices - Application of Risk Management to Medical Devices
62304:2006	IEC EN	Medical device software - Software life-cycle processes
EC57:1998	AANSI/AAMI	Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
Guidance	FDA	Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm
Guidance	FDA	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Conclusion

The results of the above testing met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the modifications made to the Reveal LINQ Model LNQ11 Insertable Cardiac Monitor described in this submission result in a device that is substantially equivalent to the predicate.