



Food and Drug Administration  
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April 22, 2016

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

Re: K160689  
Trade/Device Name: Reveal LINQ 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: March 24, 2016  
Received: March 25, 2016

Dear 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 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

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)  
K160689

Device Name  
Reveal LINQ™ 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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## 510(k) Summary

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[As required by 21 CFR 807.92]

**Date Prepared:** March 23, 2016

**Submitter:** Medtronic, Inc.  
Medtronic Cardiac Rhythm Heart Failure  
8200 Coral Sea Street N.E.  
Mounds View, MN 55112  
Establishment Registration Number: 2182208

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### General Information

**Trade Name:** Reveal LINQ™ 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 LNQ11 Insertable Cardiac Monitor (K150614)**

## **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.

## **Indications for Use**

There are no changes to the Indications for Use. 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***

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

## **Technological Characteristics**

When compared to the predicate device (**K150614**), the modified Reveal LINQ model LNQ11 presented in this submission has the same:

- Intended use/indications for use
- Operating principle
- Design features
- Device functionality
- Biological safety
- Packaging materials
- Shelf life

The modified Reveal LINQ model LNQ11 and the predicate device differ in the following:

- Modify the Recommended Replacement Time (RRT) algorithm

- Minor update to the power supply management (K-factor) behavior to improve the power supply management efficiency.

### ***Substantial Equivalence and Summary of Studies:***

Technological differences between the subject and predicate devices have been evaluated through bench tests to provide evidence of safe and effective use. The modified Reveal LINQ Model LNQ11 Insertable Cardiac Monitor is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use.

The following standards and guidance were used for development and testing of this change:

| <b>Standard Number</b> | <b>Standard Organization</b> | <b>Standard Title</b>  |
|------------------------|------------------------------|--|
| 14971:2012             | ISO                          | Medical Devices - Application of Risk Management to Medical Devices  |
| 62304:2008             | IEC EN                       | Medical device software - Software life-cycle processes  |
| <i>Guidance</i>        | FDA                          | Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm Document Issued on October 28, 2003               |
| <i>Guidance</i>        | FDA                          | Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005 |

### **Summary of Testing**

Firmware regression testing, design verification and system design validation testing were performed to demonstrate the Reveal LINQ ICM meet established performance criteria to support equivalency to the referenced predicate device.

### ***Performance Testing – Bench***

- Firmware Regression Verification Testing – Verification testing performed for the Reveal LINQ Firmware with LINQ RRT modification and minor enhancements is complete. All 870 regression tests were executed and passed.
- Design Verification – No system or product level requirements were modified by this submission. Therefore, design verification was completed by verifying similarity to a previous design. The design outputs meet the design inputs based on: system and finished device similarity to the previous design(s), verification of the previous design(s), verification of no unintended changes to the current design(s), and verification of no unintended RAMware/firmware interactions within the finished device. All acceptance criteria have been met. The Reveal LINQ System and Reveal LINQ Insertable Cardiac Monitor are considered verified against their design input requirements.
- System Design Validation – System Design Validation Plan, activities fell into two general categories: analyses and test execution. Test protocols were developed to provide coverage of

the aspects of the system being validated against the design input requirements and risk control measures being validated.

## **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.