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, 2017

Medtronic Inc.
Laura Danielson
Principal Regulatory Affairs Specialist
8200 Coral Sea St NE
Mounds View, Minnesota 55112

Re: K163460
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: December 8, 2016
Received: December 9, 2016

Dear Laura Danielson:

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.

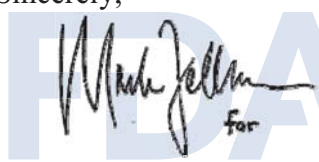
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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)*
K163460

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared:	13 February 2017
510(k) Owner / Address:	Medtronic, Inc. Cardiac Rhythm and Heart Failure 8200 Coral Sea Street Mounds View, MN 55112
Contact:	Laura L. Danielson Principal Regulatory Affairs Specialist
Telephone:	(763) 526-2385
Fax:	(651) 367-0603
E-mail:	laura.l.danielson@medtronic.com
Trade / Proprietary Name:	Reveal® LINQ™ Insertable Cardiac Monitor, Model LNQ11
Common Name:	Insertable Cardiac Monitor
Classification / Classification Name:	Class II 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 LINQ Mobile Manager Application (Model MSW001 or MSW002) and patient connector (Model 24965 and 24967) (referred to as the LINQ Mobile Manager system) are substantially equivalent to the following predicate device:

- Reveal LINQ ICM (Model LNQ11) cleared via K160689 on April 22, 2016.

Indications for Use Comparison to the Predicate

The indications for use remains unchanged from the predicate and are 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.

Comparison of Technological Characteristics with Predicate Device

The following table contains a comparison of the CareLink SmartSync Device Manager patient connector, Model 24967 to the predicate device (Model 24965) with no differences.

Predicate Comparisons

	Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 or MSW002 and existing patient connector Model 24965)	**Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 and MSW002 and additional patient connector Model 24967)**
Manufacturer	Medtronic, Inc.	Medtronic, Inc.
510(k) Number	K160809	KXXXXXX
Model Number	LNQ11	LNQ11
Intended Use	Same (See **Indications for Use Form 3881)**	Same (See **Indications for Use Form 3881)**
Ambulatory ECG Monitor	Same	Same
Continually Record ECG Information?	Same	Same
Record Pre- & post-event	Same	Same
R Wave Sensing Sampling Rate	Same Same	Same Same
Storage Time	Same	Same
Noise Reversion	Same	Same
Brady Detection	Same	Same
Asystole Detection	Same	Same
Ventricular Tachycardia Detection	Same	Same
Patient Activated & Auto Activated	Same	Same
Atrial Tachyarrhythmia Monitoring & Diagnostics	Same	Same
Day & Night Heart Rate Diagnostics	Same	Same
Afib Detection	Same	Same
Heart Rate Variability Algorithm & Diagnostics	Same	Same
Telemetry	Same	Same
Activity Monitoring	Same	Same
Longevity	Same	Same
Electrode Spacing (inside-to-inside)	Same	Same

	Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 or MSW002 and existing patient connector Model 24965)	Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 and MSW002 and additional patient connector Model 24967)
Volume	Same	Same
Mass	Same	Same
Episode Storage	Same	Same
Patient Symptom Mark	Same	Same
Cardiac Compass	Same	Same
MRI Compatibility	Same	Same
Clinician Notification	Same	Same
Bi-Directional Telemetry	Same	Same
Detection Algorithms	Same	Same
CareLink	Same	Same
Wireless Telemetry	Same	Same
Patient's CareLink Clinic Name and ID	Yes	Yes

The following patient contacting material comparison demonstrates substantial equivalence between patient contacting materials. Information on differences can be found in the paragraph following the table.

Patient Contacting Material Comparison

Component	Material	Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 or MSW002 and existing patient connector Model 24965)	Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 and MSW002 and additional patient connector Model 24967)
Can	Titanium	Yes	Yes
Electrodes	Titanium nitride	Yes	Yes
Header	Polyurethane, silicone	Yes	Yes
Coating	Parylene	Yes	Yes

Component	Material	Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 or MSW002 and existing patient connector Model 24965)	Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 and MSW002 and additional patient connector Model 24967)
Telemetry Head	Amorphous thermal plastics, thermal plastic elastomer, silicone rubber and polyester film	Polycarbonate Lexan	Silicone rubber Rogers Bisco HT-6240, clear Polycarbonate Sabic Lexan EXL9330 with 8T9D168 white colorant (Medtronic color chip M954239A001) Silicone rubber Wacker Elastosil LR 3003/60, color chip SP 50812 (blue) Silicone rubber Momentive TSE221 per color chip Pantone Cool Grey 8 button; polyester Autotex V200 clear (back screened) with hard coated top surface and velvet finish graphics

Telemetry Head Material

The housing material of the CareLink SmartSync Device Manager patient connector is polycarbonate. The use of polycarbonate boosts chemical resistance concerning exposure to repeat cleaning and disinfection.

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the CareLink SmartSync Device Manager, patient connector, Model 24967 was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing for materials used in the Model 24967 included the following tests:

- Cytotoxicity

- Sensitization
- Irritation

The Model 24967 has acute duration of skin contact with the patient, and is not implanted.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the CareLink SmartSync Device Manager, patient connector, Model 24967, associated applications and non-medical mobile platform (i.e. Tablet) with associated cables as necessary for test. The system complies with the IEC 60601-1, standards for safety and the IEC 60601-1-2 third and fourth edition versions of the standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Mechanical Testing

The following is a list of testing performed:

- Inspection of the required mechanical design features and function
- Workmanship inspection concerning all external surfaces that can cause injury such as sharp edges or pinch points
- Product labeling inspection
- Forces required to activate controls
- Chemical resistance testing for effects of repeat cleaning cycles
- Environmental and drop testing
- Reliability testing of buttons, electrical contacts, user connector insertions, and replaceable or moving mechanical components

Animal Study

There were no formalized animal studies performed for this 510(k) submission.

Clinical Studies

There were no formalized clinical studies performed for this 510(k) submission.

Conclusions

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the CareLink SmartSync Device Manager, patient connector, Model 24967 should perform as intended in the specified use conditions.