April 5, 2023

Medtronic, Inc.
Kerry Luyster
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K223630
Trade/Device Name: Reveal LINQ Insertable Cardiac Monitor (ICM) with AccuRhythm AI ECG Classification System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MXD
Dated: March 3, 2023
Received: March 6, 2023

Dear Kerry Luyster:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Sara M. Royce -S Digitally signed by Sara M. Royce -S Date: 2023.04.05 14:20:21 -04'00'

Hetal Odobasic
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223630

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

Date Prepared: April 5, 2023

Submitter: Medtronic, Inc.
Cardiovascular Diagnostics and Services
8200 Coral Sea Street NE
Mounds View, MN 55112
Establishment Registration Number: 2182208

Contact Person: Kerry C Luyster
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General Information

Trade Name: Reveal® LINQ™ Insertable Cardiac Monitor (ICM) with AccuRhythm AI ECG Classification System

Common Name: Insertable Cardiac Monitor

Regulation Number: CFR 870.1025

Product Code: MXD

Classification: Class II

Classification Panel: Cardiovascular

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

Predicate Device: LINQ II ICM, Model LNQ22, with AccuRhythm AI ECG Classification System (K210484)

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.

Reveal LINQ ICM includes the following accessories: LINQ Tool Kit Model LNQTOOL, Patient Assistant PA96000, Reveal LINQ™ Mobile Manager Model MSW002 used with Patient Connector Model 24967, CareLink Programmer Model 2090, Encore Programmer Model 29901, Reveal LINQ Application Software Model SW026, MyCareLink Patient Monitor Models 24950 and 24955, CareLink Express Monitor Model 2020B, Device Data Management Application Model 2491, Device Command Library Model 2692 and Instrument Command Library Model 2691, CareLink Express Mobile Application Models 31301 and 31302, and CareLink Network. New to the Reveal LINQ ICM system is the AccuRhythm AI ECG Classification System Models ZA400, ZA410, ZA420, included in this submission.

Indications for Use

There are no changes to the Indications for Use for the Reveal LINQ ICM device as a result of this submission. The subject device Reveal LINQ ICM when used with the AccuRhythm AI ECG Classification System has the same indications for use as the predicate device (K210484). 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

Substantial equivalence between the Reveal LINQ ICM and LINQ II ICM was established in K200795 (03JUL2020). There are no attribute changes to the device as part of this 510(k) Notification, other than the addition of AccuRhythm AI to the Reveal LINQ ICM ecosystem.

There is no change in the design and technology of the Reveal LINQ ICM or the LINQ II ICM device, other than the addition of AccuRhythm AI ECG Classification System to the Reveal LINQ ICM ecosystem. The subject device Reveal LINQ ICM when used with the AccuRhythm AI ECG Classification System has the same operating principle, device technology and functionality, indications for use and biological safety as the predicate device LINQ II with AccuRhythm AI ECG Classification System (K210484).

Substantial Equivalence

Differences between the subject and predicate devices have been evaluated through bench testing to provide evidence of substantial equivalence. The Reveal LINQ ICM when used with the AccuRhythm AI ECG Classification System is substantially equivalent to the predicate LINQ II ICM with AccuRhythm AI ECG Classification System (K210484) based on comparisons of indications for use, operating principle, device technology and functionality, and safety.

Summary of Testing

Design verification and design validation were performed to demonstrate that the Reveal LINQ ICM when used with the AccuRhythm AI ECG Classification System met both design requirements and established performance criteria to support substantial equivalence to the predicate LINQ II ICM with AccuRhythm AI ECG Classification System (K210484).

- **Design Verification:** Software design verification was completed to ensure the design output meets specifications outlined in the design inputs. The AccuRhythm ECG Classification System meets the functionality per the requirements and all test executions resulted in a status of Passed.
- **Design Validation:** Performance validation testing and analysis were completed to ensure the algorithms were able to reduce false alerts from ICM detected AF and Pause episodes while retaining true alerts. All results met or exceeded the criteria in the Validation Plan.

Since there were no changes to the Reveal LINQ ICM itself, there was no development or testing specific to the ICM; therefore, no standards are referenced for the Reveal LINQ ICM.

The following standards were used for development and testing of the AccuRhythm AI ECG Classification System.

Standard Number	Standard Organization	Recognition Number	Standard Title
14971:2019	ISO	5-125	Medical Devices - Application of Risk Management to Medical Devices
15223-1:2016	ISO	5-117	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
82304-1:2017	IEC	13-97	Health software — Part 1: General requirements for product safety
62304:2006/ AMD 1:2015	IEC	13-79	Medical device software - Software life cycle processes
62304:2006/AC:2008	IEC	13-79	Medical device software - Software life cycle processes

Standard Number	Standard Organization	Recognition Number	Standard Title
EC57: 2012	ANSI/AAMI	3-118	Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms

Conclusion

The results of the testing met the design requirements and specified acceptance criteria and did not raise new safety or performance issues. Therefore, the Reveal LINQ ICM Model LNQ11 when used with the AccuRhythm AI ECG Classification System Models ZA400, ZA410, ZA420 described in this submission results in a device that is substantially equivalent to the predicate LINQ II ICM, Model LNQ22, with AccuRhythm AI ECG Classification System (K210484).