July 22, 2021

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

Re: K212008
Trade/Device Name: Reveal LINQ Insertable Cardiac Monitor
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: June 24, 2021
Received: June 28, 2021

Dear Andrea Artman:

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,

Jennifer Shih
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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)*
K212008

Device Name
Reveal LINQ Insertable Cardiac Monitor (ICM)

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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: June 25, 2021

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

Contact Person: Andrea Artman
Principal Regulatory Affairs Specialist
Medtronic Cardiovascular Diagnostics & Services
Phone: 419.708.4172
Fax: 651.367.0603
Email: andrea.p.artman@medtronic.com

Alternate Contact: Ryan Calabrese
Senior Director Regulatory Affairs
Medtronic Cardiovascular Diagnostics & Services
Phone: 763.234.3574
Fax: 651.367.0603
Email: ryan.s.calabrese@medtronic.com

General Information

Trade Name: Reveal® LINQ™ Insertable Cardiac Monitor (ICM)

Common Name: Insertable Cardiac Monitor

Regulation Number: 21 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: Reveal® LINQ™ Insertable Cardiac Monitor (ICM), Model LNQ11 (K162855)

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

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

When compared to the predicate device (K162855), the modified Reveal LINQ Insertable Cardiac Monitor 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 ICM device differs from the predicate in that the modified device contains added RAMware to ensure the detection parameters are appropriately configured after a partial electrical reset.

Substantial Equivalence and Summary of Studies

Technological differences between the subject and predicate devices have been evaluated with device verification and system validation testing. The objective evidence from the verification and validation testing confirm that the change adequately mitigates incorrect rejection parameter settings.

The modified Reveal LINQ 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 modifications to the subject device were verified and validated through design verification and validation activities. All design verification and design validation activities were completed successfully and demonstrated there was no adverse impact to the functioning of the modified Reveal LINQ ICM device.

Conclusion

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