December 6, 2023

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

Re: K233562
Trade/Device Name: LINQ II 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: November 6, 2023
Received: November 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica L. Batista -S

Digitally signed by Jessica L. Batista -S
Date: 2023.12.06 15:36:19 -05'00'

for

Sara Royce
Acting 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233562

Device Name

LINQ II Insertable Cardiac Monitor

Indications for Use *(Describe)*

The LINQ II ICM is an insertable automatically-activated and patient activated monitoring system that records subcutaneous ECG and is indicated in adult patients, and in pediatric patients who are at least 2 years old, 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

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.

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510(k) Summary

Date Prepared: November 6, 2023

Submitter: Medtronic, Inc.
Cardiac Rhythm Management
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: LINQ II™ Insertable Cardiac Monitor

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™ Insertable Cardiac Monitor (Model LNQ22) K233320

Device Description

The LINQ II Insertable Cardiac Monitor (ICM) Model LNQ22 is a programmable device that continuously monitors a patient's ECG and other physiological parameters. The device records cardiac information in response to automatically detected arrhythmias and patient-initiated activation or markings. The device is designed to automatically record the occurrence of an episode of arrhythmia in a patient. Note: Arrhythmias are classified as tachyarrhythmia, bradyarrhythmia, pause, atrial tachyarrhythmia, or atrial fibrillation. Patients may also manually record symptoms. In order to manually record symptoms, the patient will also need either the MyCareLink Heart App (patient app on mobile device) or the Patient Assistant Model PA97000. The patient can use the MyCareLink Heart App or the Patient Assistant to manually record his or her cardiac rhythm while experiencing or immediately after a symptomatic event. LINQ II ICM includes the following accessories: LINQ II Tool Kit Model LNQ22TK, Reveal LINQ™ Mobile Manager Model MSW002, Device Command Library Model 2692, Instrument Command Library Model 2691, and AccuRhythm AI ECG Classification System Models ZA400, ZA410, ZA420 and CareLink SmartSync LINQ II ICM Application Model D00U024. New to the LINQ II ICM system is the CareLink SmartSync LINQ II Platform Application Model D00U027.

Indications for Use

The LINQ II ICM Indications for Use remain the same as a result of this submission and are as follows:

> The LINQ II ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in adult patients, and in pediatric patients who are at least 2 years old, 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

Technological Characteristics

The LINQ II ICM consists of a hybrid substrate that is made of sapphire. The sapphire provides part of the implantable hermetic enclosure, integrates the feedthroughs directly into the substrate, and provides a substrate for component attachment/interconnect. The antenna and sense electrodes are titanium foil laser bonded to the outside of the sapphire substrate and connected directly to the embedded feedthroughs. The sense electrodes are coated with sputtered titanium nitride. The sapphire is laser bonded to the titanium battery cover, which provides the complete hermetic enclosure. The battery is Lithium anode, silver vanadium oxide/carbon monofluoride cathode with a capacity of 167 mAh.

The LINQ II ICM will continue to use the same technology. It is designed to automatically record the occurrence of an arrhythmia in a patient, continuously sense the patient's subcutaneous ECG, and analyze the timing of ventricular events to detect possible episodes of arrhythmia. The LINQ II ICM has a small form factor, and uses Sapphire, Titanium, Parylene, and Titanium Nitride coating on the sensing electrodes as body contacting materials.

When compared to the predicate LINQ II ICM (K233320), the LINQ II ICM when used with the CareLink SmartSync LINQ II Platform Application has the same indications for use, operating principle, device technology and functionality, and biological safety.

When compared to the predicate LINQ II ICM (K233320), the LINQ II ICM differs only in its use with the CareLink SmartSync LINQ II Platform Application.

Substantial Equivalence

Differences between the subject and predicate devices have been evaluated through bench testing to provide evidence of substantial equivalence. The LINQ II ICM when used with the CareLink SmartSync LINQ II Platform Application is substantially equivalent to the predicate LINQ II ICM (K233320) 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 LINQ II ICM when used with the CareLink SmartSync LINQ II Platform Application met design requirements and established performance criteria to support substantial equivalence to the predicate LINQ II ICM (K233320).

- **Design Verification:** Software and system design verification were completed to ensure the design output meets specifications outlined in the design inputs. The CareLink SmartSync LINQ II Platform Application meets the functionality per the requirements and all test executions resulted in a status of Passed.
- **Design Validation:** System validation review was completed to ensure the CareLink SmartSync LINQ II Platform Application meets design input requirements under actual or simulated use conditions. All results met the criteria in the Validation Plan.

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

The following standards were used for development and testing of the CareLink SmartSync LINQ II Platform Application.

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

Standard Number	Standard Organization	Recognition Number	Standard Title
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

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 LINQ II ICM Model LNQ22 when used with the CareLink SmartSync LINQ II Platform Application Model D00U027 described in this submission results in a device that is substantially equivalent to the predicate LINQ II ICM Model LNQ22 (K233320).