



October 31, 2023

Medtronic, Inc.
Dustin Hawbaker
Sr. Prin. Regulatory Affairs Specialist
Cardiovascular Diagnostics and Services
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K233320

Trade/Device Name: LINQ II™ Insertable Cardiac Monitor (LNQ22)
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: September 29, 2023
Received: October 27, 2023

Dear Dustin Hawbaker:

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: 2023.10.31
10:44:34 -04'00'

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

Indications for Use

Submission Number (if known)

K233320

Device Name

LINQ II™ Insertable Cardiac Monitor (LNQ22)

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.

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510(k) Summary

Submitter Information

Date Prepared: September 28, 2023

Submitter: Medtronic, Inc.
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General Information

Trade Name: LINQ II™ Insertable Cardiac Monitor (LNQ22)

Common Name: Insertable Cardiac Monitor

Regulation Number: 21 CFR 870.1025

Product Code: MXD

Classification: Class II

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

Predicate Device: LINQ™ II Insertable Cardiac Monitor (Model LNQ22) K221962

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. 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.

Accessories

The LINQ II ICM includes the following accessories:

- The LINQ Tool Kit Model LNQ22TK includes two implant tools: The Incision Tool is used to make a small incision through the patient's skin; and the Insertion Tool is used to insert the device through the incision and into the patient's body at the desired location.
- The Reveal LINQ™ Mobile Manager (LMM) Model MSW002 is the programmer designed as a mobile app that communicates with the Reveal LINQ and LINQ II ICM devices via the existing model 24967 telemetry head.
- The 2692 Device Command Library (DCL) software is a component of the Data Transformation Services subsystem of the CareLink Network. This software is responsible for understanding command status, implant device state within CareLink, and the initiation of commands for the implanted device.
- The 2691 Instrument Command Library (ICL) software is the logic and data files required for remote programming.

Indications for Use

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 predicate 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 subject 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 (K221962), the modified LINQ II ICM described herein has the same:

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

The modified LINQ II ICM differs from the predicate in that the modified device introduces a new Firmware (FW) solution to replace the current LINQ II ICM FW, enabling faster integration of future enhancements, manufacturing efficiencies, and quality improvements for the market-released LINQ II ICM system.

Substantial Equivalence

Technological differences between the subject and predicate devices have been evaluated with design verification and validation testing. The objective evidence from testing provides assurance of substantial equivalence.

The modified LINQ II ICM 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 verification and validation activities were completed successfully and demonstrated there was no adverse impact to the function of the modified LINQ II ICM.

Conclusion

The results of verification and validation testing met pre-determined acceptance criteria and did not raise new safety or performance issues. Therefore, the modifications made to the LINQ II ICM described herein result in a device that is substantially equivalent to the predicate.