August 25, 2022

Medtronic, Inc.
Dianna Johannson
Distinguished Regulatory Affairs Advisor
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K221962
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: July 1, 2022
Received: July 5, 2022

Dear Dianna Johannson:

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,

Hetal Odobasic
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)*
K221962

Device Name
LINQ II Insertable Cardiac Monitor (Model 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: July 1, 2022

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General Information

Trade Name: LINQ™ II

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 (K200795)

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 medical accessories: LINQ Tool Kit Model LNQ22TK, Patient Assistant Model PA97000, Reveal LINQ™ Mobile Manager Model MSW002 with patient connector Model 24967, Device Command Library Model 2692, Instrument Command Library Model 2691, and the Zelda (AccuRhythm) AI ECG Classification System Models ZA400, ZA410, and ZA420.

Indications for Use

The LINQ II ICM Indications for Use statement is impacted as a result of this submission and is 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 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 (K200795), the LINQ II ICM with the proposed labeling changes has the same operating principle, device technology and functionality, and safety.

When compared to the predicate LINQ II ICM (K200795), the LINQ II ICM differs only in its updated labeling to extend the existing indications for use to the pediatric patient population, and

to expand the MRI conditions for use from a static magnetic field of 1.5 T or 3.0 T to static magnetic fields of ≤ 3 T.

Substantial Equivalence

Differences between the subject and predicate devices have been evaluated through impact analyses, MRI bench testing, pediatric clinical evaluation, and risk management activities to provide evidence of safe and effective use. The LINQ II ICM with the proposed labeling changes is substantially equivalent to the predicate LINQ II ICM (K200795) based on comparisons of indications for use, operating principle, device technology and functionality, and safety.

Summary of Testing

The design process for the proposed labeling updates involved requirements review, impact analyses, risk management activities, design verification and validation, and clinical evaluation to demonstrate that the LINQ II ICM with the proposed labeling changes met design requirements, is safe and effective for use in the pediatric patient population, and is substantially equivalent to the predicate LINQ II ICM (K200795).

- **Design Verification:** Electrical device verification testing was conducted for Low Field MRI test conditions and test protocols to ensure that the product operated as expected. The test executions resulted in a status of Pass and all test results and rationale demonstrate the final set of electrical requirements are met.
- **Design Validation:** Updates to design input requirements were validated. Design validation acceptance criteria have been met, and the requirements meet the stakeholder needs.
- **Clinical Evaluation:** A retrospective clinical evaluation of published literature, post-market surveillance data, and studies was performed to assess the safety and effectiveness of the LINQ II ICM existing indications for use in the pediatric patient population.

The following standards were referenced for this project.

Standard Number	Standard Organization	Recognition Number	Standard Title/CS Title
14971:2019	ISO	5-125	Medical devices - Application of risk management to medical devices
20417:2021	ISO	15-135	Medical Device-Information supplied by the manufacturer
10993-1:2020	ISO	2-258	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
10993-7:2008/AC:2009	ISO	14-408	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
11135:2014 +A1:2019	ISO	14-529	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices Amendment 1: Revision of Annex E, Single batch release
45502-1:2015	EN	Not recognized	Implants for surgery - Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer

Conclusion

The results of the impact analyses, risk management activities, design verification and validation, and clinical evaluation concluded the design requirements and specified acceptance criteria were met and the proposed labeling changes did not raise new safety or effectiveness issues. Therefore, the LINQ II ICM Model LNQ22 with the proposed labeling changes described in this submission results in a device that is substantially equivalent to the predicate LINQ II ICM Model LNQ22 (K200795).