June 11, 2021

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

Re: K210484
Trade/Device Name: LINQ II Insertable Cardiac Monitor, Zelda 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: May 11, 2021
Received: May 12, 2021

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,

Jennifer Shih Kozen
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)*
K210484

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 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.

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# 510(k) Summary

**Date Prepared:** February 16, 2021

**Submitter:** Medtronic, Inc.
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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 accessories: LINQ Tool Kit Model LNQ22TK, Reveal LINQ™ Mobile Manager Model MSW002, Device Command Library Model 2692, and Instrument Command Library Model 2691. New to the LINQ II ICM system is the Zelda AI ECG Classification System Models ZA400, ZA410, ZA420, included in this submission.

## Indications for Use

The LINQ II ICM Indications for Use remains 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 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

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 (K200795), the LINQ II ICM when used with the Zelda AI ECG Classification System has the same Indications for Use, operating principle, device technology and functionality, and biological safety.

When compared to the predicate LINQ II ICM (K200795), the LINQ II ICM differs only in its use with the Zelda AI ECG Classification System.

## Substantial Equivalence

Differences between the subject and predicate devices have been evaluated through bench testing to provide evidence of safe and effective use. The LINQ II ICM when used with the Zelda AI ECG Classification System 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

Design verification and design validation were performed to demonstrate that the LINQ II ICM when used with the Zelda AI ECG Classification System met both design requirements and established performance criteria to support substantial equivalence to the predicate LINQ II ICM (K200795).

- **Design Verification:** Software design verification was completed to ensure the design output meets specifications outlined in the design inputs. The Zelda 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 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 Zelda 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 |
| 82304-1:2016 | 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 |
| EC57: 2012 | ANSI/AAMI | 3-118 | Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms |
| 60601-1:2005 / A1:2012 | AAMI/ANSI | 19-4 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Clause 14) (IEC 60601-1:2005, mod) |

## Predetermined Change Control Plan

The Zelda AI ECG Classification System is powered by deep-learning neural architectures for AF and Pause detection based on the residual convolutional neural network and ensemble models. Medtronic will make future algorithm improvements under a Predetermined Change Control Plan (PCCP). In the plan, a protocol was provided to specify the methods to achieve and appropriately control the risks of the anticipated types of modifications described in the Software as a Medical Device (SaMD) Pre-specifications (SPS). The planned changes include 1) changing the threshold, 2) re-training the algorithm on data labeled following the original protocol and data labeled following an alternate protocol, 3) pre-training the algorithm. Assessment metrics, acceptance criteria, and statistical methods have been described for the performance testing of the proposed changes. Information on the deployment and post market surveillance of the algorithm are also provided for the proposed changes.

## 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 Zelda 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 (K200795).

The proposed modifications in the predetermined change control plan (PCCP) of the 510(k) submission outlined anticipated modifications to the Zelda AI ECG Classification System Models ZA400, ZA410, ZA420, and the methods that will be utilized to implement those modifications in a controlled and deliberate manner while maintaining safety and efficacy. In accordance with the PCCP, market release of any modifications will only occur after the modified algorithms are proven to achieve superior performance, increasing sensitivity and/or specificity, while maintaining or improving other performance metrics. The PCCP does not include provisions for implementation of adaptive algorithms that will continuously learn in the field and all algorithm modifications will be locked prior to release to the field.