August 28, 2026

Medtronic, Inc.
Shreya Chenni
Sr. Regulatory Affairs Specialist
8200 Coral Sea St.
Mounds View, Minnesota 55340

Re: K262735
Trade/Device Name: LINQ II Insertable Cardiac Monitor (ICM) (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: July 31, 2026
Received: July 31, 2026

Dear Shreya Chenni:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

ALEXANDRA K. MANARAS -S

Alexandra Manaras
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262735

Please provide the device trade name(s).

LINQ II Insertable Cardiac Monitor (ICM) (LNQ22)

Please provide your Indications for Use below.

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
-patients who have been previously diagnosed with or treated for atrial or ventricular arrhythmias

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Submitter Information

Date Prepared:	8/28/2026
Submitter	Medtronic, Inc.
	Cardiac Rhythm Management 8200 Coral Sea Street NE Mounds View, MN 55112 ERN: 2182208
Contact Person	Shreya Chenni Sr. Regulatory Affairs Specialist Email: shreya.chenni@medtronic.com Phone: +12025692535
Alternate Contact	Haley Liberty Prin. Regulatory Affairs Specialist Email: haley.liberty@medtronic.com Phone: +17635262359

General Information

Trade name: LINQ II™ Insertable Cardiac Monitor
Common name: Insertable cardiac monitor
Product code: MXD
Classification: Class II
Regulation number: 21 CFR 870.1025
Special Controls: Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm
Predicate Device: LINQ II™ Insertable Cardiac Monitor (model LNQ22) K240693

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 a programmer designed as a mobile app that communicates with the 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 indications for use for the modified LINQ II ICM are:

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, andchest pain that may suggest a cardiac arrhythmia
- patients who have been previously diagnosed with or treated for atrial or ventricular arrhythmias

The modified LINQ II ICM has an indication for use statement that differs from the predicate device. The statement was revised to provide additional clarity regarding the patient population, but it does not introduce a new patient population or a new disease. The modified LINQ II device continues to have the same intended diagnostic use as the predicate device, and this update does not result in any new or increased risks.

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 (K240693), the modified LINQ II ICM described herein has the same:

- 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 includes a new via fill material.

Substantial Equivalence

The modified LINQ II ICM is substantially equivalent to its predicate device based on the comparisons of the device functionality, technology characteristics and intended use. The changes to the subject device were verified through design verification activities. Testing demonstrated that the new via fill material and associated manufacturing changes do not adversely impact the safety, performance, or reliability of the LINQ II ICM device.

All verification activities were completed successfully and demonstrated there was no adverse impact to the function of the subject device. The verification results did not raise new safety concerns or performance issues.

Conclusion

Based on the intended use, fundamental technological characteristics, and results of verification activities, the subject device has demonstrated to be substantially equivalent to the predicate device.