May 17, 2023

Abbott Medical
Laura Sparks
Project Manager, Regulatory Affairs
15900 Valley View Ct.
Sylmar, California 91342

Re: K230286
Trade/Device Name: Assert-IQ™ Insertable Cardiac Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MXC, DSI
Dated: April 14, 2023
Received: April 17, 2023

Dear Laura Sparks:

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,

for Sara M. Royce -S
Digitally signed by Sara M. Royce -S
Date: 2023.05.17 10:43:48 -04'00'

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)*
K230286

Device Name
Assert-IQ™ Insertable Cardiac Monitor

Indications for Use *(Describe)*
The Assert-IQ™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms that may be cardiac-related such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias such as bradycardia, tachycardia, and sinus pauses. The Assert-IQ ICM is also indicated for patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF. The Assert-IQ ICM is intended to be inserted subcutaneously in the left pectoral region, also described as the left anterior chest wall. The Assert-IQ ICM has not been specifically tested 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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K230286
510(k) SUMMARY

Date Prepared:	February 1, 2023	
Submitter:	Abbott Medical	
Address:	15900 Valley View Ct. Sylmar, CA 91342 USA	
Phone:	(818) 362-6822	
Establishment Registration:	2017865	
Contact Person:	Laura Sparks Project Manager, Regulatory (818) 493-2734 laura.sparks@abbott.com	Jennifer Dunham Assoc. Director, Regulatory (818) 383-1630 jennifer.dunham@abbott.com
Trade Name/Proprietary	Assert-IQ™ Insertable Cardiac Monitor	
Common Name:	Insertable Cardiac Monitor	
Model Numbers:	DM5000, DM5300, DM5500	
Classification Name:	21 CFR 870.2800, Medical magnetic tape recorder	
Product Code:	MXC, DSI	
Classification:	Class II	
Pediatric Use:	The Assert-IQ™ Insertable Cardiac Monitor has not been specifically tested for pediatric use.	

LEGALLY MARKETED DEVICE TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

510(k) K212206 Jot Dx™ Insertable Cardiac Monitor

INDICATIONS FOR USE

The Indications for Use for the Assert-IQ™ Insertable Cardiac Monitor (ICM) is as follows:

> The Assert-IQ ™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms that may be cardiac-related such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias such as bradycardia, tachycardia, and sinus pauses. The Assert-IQ ICM is also indicated for patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF. The Assert-IQ ICM is intended to be inserted subcutaneously in the left pectoral region, also described as the left anterior chest wall. The Assert-IQ ICM has not been specifically tested for pediatric use.

K230286
510(k) SUMMARY

PRODUCT DESCRIPTION

The Assert-IQ™ ICM system consists of Insertable Cardiac Monitor device models DM5000, DM5300, and DM5500 and is intended to help physicians monitor, diagnose, and document the rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms, as indicated.

Specific features include:

- Patient-initiated triggering of EGM storage using the myMerlin™ mobile application. This includes capability for the patient to identify symptoms, which are stored with the EGM for physician review.
- Automated triggering of EGM storage when tachycardia, bradycardia, or pauses are detected; with physician-programmable values for pause duration, bradycardia rate, tachycardia rate, and number of tachycardia intervals.
- Automated triggering of EGM storage when atrial fibrillation (AF) is detected, with physician programmable values for AF duration.
- The ability to inhibit EGM storage due to noise and allow for detection and storage of AF and non-AF (pause, bradycardia, and tachycardia) arrhythmias after noise exit.
- Collection and display of diagnostic trends, including AF burden, PVC burden, and activity trends.
- Remote monitoring capability
- Remote programming capability

The Assert-IQ ICM system includes the ICM device and the following key components, which are within the scope of this premarket submission.

- Delivery/Implant Tools (Incision Tool model DM5320 and Insertion Tool model DM5310 or DM5510) – used to implant the ICM device subcutaneously. The implantable device is pre-loaded into the associated insertion tool and packaged together with the incision tool.
- myMerlin™ mobile application (model APP1000 (Android) or APP1001 (iOS)) – provides the means for the patient to activate EGM recording in the Assert-IQ™ ICM device, with data pass-through functionality to enable physician follow-up and remote programming via the Merlin.net Patient Care Network.
- Merlin.net™ Software, model MN7000 – Virtual Device Engine (VDE), which includes services for user parameter management and updates to support remote programming of Assert-IQ™ ICM devices.

K230286
510(k) SUMMARY

TECHNOLOGICAL CHARACTERISTICS

The fundamental technology of the Assert-IQ™ ICM, relative to the predicate Jot Dx™ ICM (K212206), is not changing.

An overview of some design/technological characteristics of the predicate Jot Dx ICM DM4500 (K212206) and the subject Assert-IQ ICM devices follows (refer to Section 11 for details).

- Improved longevity—subject Assert-IQ ICM model DM5500 has a 6-year longevity, and subject Assert-IQ ICM models DM5000 and DM5300 have a 3-year longevity. The predicate device model DM4500 has a 2-year longevity.
- The subject Assert-IQ ICM models DM5300 and DM5500 support remote programming, while the predicate device model DM4500 and subject Assert-IQ ICM model DM5000 do not.
- The subject and predicate devices support remote monitoring.
- 1.5T and 3T MR Conditional labeling (subject and predicate)
- Assert-IQ ICM subject device models DM5000 and DM5300 are slightly smaller in dimensions, volume, weight, and in electrode surface area than predicate device model DM4500, while Assert-IQ ICM subject device model DM5500 is slightly larger in dimensions, volume, weight, and in electrode surface area than predicate device model DM4500.
- A suture hole is not present in the subject Assert-IQ ICM devices (present for optional use in predicate device model DM4500).
- The header electrode is dual-sided (front and back) on the subject Assert-IQ ICM devices, while the predicate model DM4500 electrode is single-sided.
- The can, electrode material, coating, and battery chemistry are the same on the subject Assert-IQ ICM and predicate model DM4500 devices, while the header material differs.
- Sterilization and packaging are the same for subject and predicate devices.
- Device telemetry using Bluetooth Low Energy is the same for subject and predicate devices.
- The subject and predicate devices support automatic arrhythmia detection and manual (patient-activated) recording.
- The subject Assert-IQ ICM devices include 3D accelerometers. Assert-IQ ICM models DM5300 and DM5500 support 3D+HS and 1D modes of operation and support posture data at episode onset. Assert-IQ ICM model DM5000 supports 1D mode of operation without support for posture data at episode onset. The predicate model DM4500 device includes a 1D accelerometer without support for posture data at episode onset.
- Additional diagnostic trends (PVC burden and activity) in the subject Assert-IQ ICM device models DM5300 and DM5500. All subject Assert-IQ ICM device models and the predicate DM4500 devices support AF burden diagnostic trends.

SUBSTANTIAL EQUIVALENCE

The subject Assert-IQ™ ICM system is substantially equivalent to the predicate Jot Dx™ ICM system (K212206).

The underlying indications for use are not impacted by the changes within the scope of this premarket submission, though minor updates have been made to the language of the indications for use of the Assert-IQ™ ICM system as compared to the predicate Jot Dx™ ICM system (K212206) for clarity and for harmonization with global labeling.

Table 1: Substantial Equivalence Indications for Use Comparison

Predicate Device Jot Dx™ ICM (K212206) Indications for Use	**Subject Device Assert-IQ™ ICM Indications for Use**
The Jot Dx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as the following: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation. The Jot Dx ICM has not been specifically tested for pediatric use.	The Assert-IQ ™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms that may be cardiac-related such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias such as bradycardia, tachycardia, and sinus pauses. The Assert-IQ ICM is also indicated for patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF. The Assert-IQ ICM is intended to be inserted subcutaneously in the left pectoral region, also described as the left anterior chest wall. The Assert-IQ ICM has not been specifically tested for pediatric use.

Both the subject and the predicate device (K212206) systems have the same fundamental functionality and technological characteristics. The changes within scope of this premarket submission do not raise new issues of safety and effectiveness. The modifications to the subject device do not alter the previously evaluated clinical acceptance criteria and were verified through design verification and system validation activities.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary device and system verification testing was conducted on the subject Assert-IQ™ ICM to support a determination of substantial equivalence to the predicate device, including:

- Software/Firmware Verification and System Verification
- Cybersecurity
- Bluetooth / coexistence
- Preclinical Testing (Animal GLP Study)
- Biocompatibility
- Sterilization
- Shelf Life
- Packaging
- Electromagnetic compatibility (EMC)
- Electrical safety
- MRI safety

- Mechanical performance
- System Validation
- Usability testing

The Assert-IQ™ ICM leverages the existing market cleared predicate (Jot Dx ICM DM4500 (K212206)) algorithms and functionality, for which the clinical testing is not repeated.

All verification and validation activities were successfully completed and did not raise new safety or performance issues; the Assert-IQ™ ICM system has been shown to be appropriate and safe for its intended use and is substantially equivalent to the predicate Jot Dx™ ICM system (K212206).

CONCLUSION

The Assert-IQ™ ICM is an implantable cardiovascular monitoring device, for which the subject device shares its fundamental design and mechanism of action, as well as the underlying indications for use, with the identified predicate Jot Dx™ ICM (K212206). The results of the verification and validation tests have demonstrated the subject Assert-IQ™ ICM in accordance with product specifications. The fundamental technology of the Assert-IQ™ ICM, relative to the predicate Jot Dx™ ICM (K212206), remains unchanged. The subject Assert-IQ™ ICM is substantially equivalent to the predicate Jot Dx™ ICM (K212206) in terms of technology, intended use, and performance.