December 18, 2025

Abbott Medical
Komal Panchal
Senior Regulatory Affairs Specialist
15900 Valley View Ct.
Sylmar, California 91342

Re: K253516
Trade/Device Name: Assert-IQ™ Insertable Cardiac Monitor System Powered by AI
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: November 10, 2025
Received: November 12, 2025

Dear Komal Panchal:

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.

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,

JESSICA L. BATISTA -S

Digitally signed by JESSICA L. BATISTA -S
Date: 2025.12.18 19:34:26 -05'00'

Jessica Batista Bertolini
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.	K253516

Please provide the device trade name(s).

Assert-IQ™ Insertable Cardiac Monitor System Powered by AI

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Date Prepared:	November 10, 2025	
Submitter:	Abbott Medical	
Address:	15900 Valley View Ct. Sylmar, CA 91342 USA	
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Contact Person:	Komal Panchal Sr. Regulatory Affairs Specialist (818) 282-8628 komal.panchal@abbott.com	Jennifer Dunham Director Regulatory Affairs (818) 383-1630 jennifer.dunham@abbott.com

Trade Name/Proprietary	Assert-IQ™ Insertable Cardiac Monitor System Powered by AI
Common Name:	Insertable Cardiac Monitor
Classification Name:	21 CFR 870.1025 -Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Product Code:	MXD
Classification:	Class II
Classification Panel:	Cardiovascular

Legally Marketed Device to Which Substantial Equivalence is Claimed

510(k) K251221 Assert-IQ™ Insertable Cardiac Monitor System Powered by AI

Indications for Use

There are no changes to the Indications for Use for the Assert-IQ Insertable Cardiac Monitor (ICM) system as a result of this submission. The Indications for Use are provided below:

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 pause. 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.

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Product Description

The Assert-IQ™ ICM system is intended to help physicians monitor, diagnose, and document the rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms, as indicated. The Assert-IQ™ Insertable Cardiac Monitor (ICM) family of Insertable Cardiac Monitor devices includes cleared models DM5000, DM5300, and DM5500. A fourth model is being included as the subject device within this 510(k)—the Assert-IQ™ 4 ICM, model DM5100.

Overview of Technological features relative to predicate (K251221) Assert-IQ™ ICM devices:

- 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 which is identical in Assert-IQ™ ICM models DM5500 and DM5000.
- 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, which is identical in Assert-IQ™ ICM models DM5500 and DM5000.
- 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, which is identical Assert-IQ™ ICM models DM5500 and DM5000.
- Collection and display of diagnostic trends, including AF burden, which is identical in Assert-IQ™ ICM models DM5500 and DM5000 and PVC burden, available in the subject device DM5100 and in model DM5500
- Remote monitoring capability, which is identical in Assert-IQ™ ICM models DM5500 and DM5000
- Remote Programming capability, which is available in the subject device DM5100 and in model DM5500.
- The subject device model DM5100 has a 4-year battery longevity, positioned between the longevity of) model DM5500 (6 years) and model DM5000 (3 years). This design change does not raise new or different questions of safety or effectiveness.
- Accelerometer in subject device model DM5100 is 1D configuration which is identical to that in model DM5000 and differs from model DM5500 (3D configuration). This configuration does not raise new or different questions of safety or effectiveness.

Substantial Equivalence

The subject Assert-IQ DM5100 is substantially equivalent to the predicate K251221. The Intended Use and Indications for use are not impacted by modifications introduced in this submission.

Both the subject device DM5100 and DM5500 is mechanically identical in hardware, form, and factor; however, the subject device DM5100 is identical to model DM5000 with regard to one technological characteristic (i.e., Activity sensor). Subject DM5100 uses the same battery as model DM5500; however, the battery in the subject device DM5100 is configured to 4-year longevity. This does not raise new or different questions of safety or effectiveness (Assert-IQ ICM family includes devices ranging from 3 years to 6 years of longevity). Verification activities were conducted for each impacted feature and/or function; based on change impact, analysis test strategy was developed to define the appropriate cross-functional test coverage. This ensures that all impacted features and functions continue to operate as intended.

Testing in Support of Substantial Equivalence Determination

All necessary design verification testing were conducted on the subject Assert-IQ DM5100 to support a determination of substantial equivalence to the predicate devices, including:

- System, device, and component-level testing confirmed DM5100 meets design specifications and performs equivalently to predicate (K251221) models.
- Mechanical Testing: Since DM5100 is mechanically identical to DM5500 hence mechanical testing is being leveraged from predicate (K251221) models.
- Device Longevity: Verified through testing under various operating modes. Although using the same battery as DM5500 (6 years), DM5100 is rated for 4 years.
- Laser Marking: Verified to meet mechanical design input requirements using established methods from the Assert-IQ family.
- Design Validation: No new clinical functionality, user needs, or intended use introduced. DM5100 uses the same hardware, firmware, and form factor as model DM5500. Existing validation activities from predicate (K251221) models (e.g., usability, algorithm performance, cybersecurity, compliance) remain applicable and sufficient.
- Usability Validation: Usability testing is being leveraged from predicate (K251221) models since no new or modified critical tasks identified.
- Biocompatibility: DM5100 is biologically identical to DM5500. No changes in materials, manufacturing, or patient-contacting components. Existing biological profile from predicate (K251221) models is applicable.
- Sterilization: DM5100 uses the same EO sterilization cycles (100 and 600) and equipment as DM5500. No new testing required due to identical materials, packaging, and processes hence testing can be leveraged from predicate (K251221) models. Meets all sterilization and microbiological requirements (e.g., SAL 10^{-6}) per ISO 11135 and internal procedures.

- Shelf life: Labeled shelf life is 18 months, same as DM5500. Identical packaging and materials allow leveraging existing shelf-life and packaging verification data from predicate (K251221) models.
- MRI Compatibility: DM5100 has the same MR Conditional labeling as DM5500 for 1.5T and 3T MRI. Shares identical hardware and firmware; only difference is 1D activity sensor calibration (vs. 3D in DM5500). No new MRI testing required; hence MRI testing can be leveraged from predicate (K251221) models.
- Cybersecurity: No changes to cybersecurity profile, controls, or risk assessments.
  No new vulnerabilities identified since last clearance (Sept 17, 2025). Cybersecurity Maintenance Plan and Software Bill of Materials (SBOM) are up to date and compliant with FDA Section 524B(b)(1) and 524B(b)(3).
- Labelling: IFU updated to include DM5100 and to include minor clarification. MRI Ready Manual updated to include DM5100 with no changes to scan conditions. Package labeling updated only for model name, number, and UDI; otherwise, consistent with models DM5500 and DM5000.

Conclusion

The Assert-IQ™ 4 ICM subject device model DM5100 shares its fundamental design and mechanism of action, as well as the underlying indications for use, with the identified predicate K251221. All verification activities were successfully completed and did not raise new or different questions of safety or effectiveness; the Assert-IQ™ 4 ICM DM5100 has been shown to be substantially equivalent to the predicate K251221.