



September 17, 2025

Abbott
Wing Yan (Winnie) Yik
Associate Director, Regulatory Affairs
15900 Valley View Ct
Sylmar, California 91342

Re: K251221

Trade/Device Name: Assert-IQ (DM5000); Assert-IQ (DM5300); Assert-IQ (DM5500); Merlin.net (MN7000)

Regulation Number: 21 CFR 870.2800

Regulation Name: Medical Magnetic Tape Recorder

Regulatory Class: Class II

Product Code: MXD

Dated: August 18, 2025

Received: August 19, 2025

Dear Wing Yan (Winnie) Yik:

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,

**ALEXANDRA K.
MANARAS -S**

For Jessica Batista Bertolini

Assistant Director

DHT2A: Division of Cardiac

Electrophysiology, Diagnostics, and
Monitoring Devices

OHT2: 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.

K251221

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Please provide the device trade name(s).

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Assert-IQ (DM5000);
Assert-IQ (DM5300);
Assert-IQ (DM5500);
Merlin.net (MN7000)

Please provide your Indications for Use below.

?

The Assert-IQ TM 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:	April 18, 2025	
Submitter:	Abbott Medical	
Address:	15900 Valley View Ct. Sylmar, CA 91342 USA	
Phone:	(818) 362-6822	
Contact Person:	Winnie Yik Assoc. Director, Regulatory (818) 322-6976 wingyan.yik@abbott.com	Laurel Jackson Regulatory Affairs Specialist (818) 509-4236 laurel.jackson1@abbott.com
Trade Name/Proprietary	Assert-IQ™ powered by AI system	
Common Name:	Assert-IQ remote care system	
Classification Name:	21 CFR 870.1025, Arrhythmia Detector and Alarm	
Product Code:	MXD	
Classification:	Class II	
Classification Panel:	Cardiovascular	
Predicate Device:	Assert-IQ™ ICM system (K230286)	

Device Description

The Assert-IQ™ ICM is designed to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review. The Assert-IQ ICM system, cleared under K230286 on May 17, 2023, includes implantable and remote care components. The implantable components include the Assert-IQ™ ICM device models DM5000, DM5300, or DM5500. The remote care portion consists of the Merlin.net™ Software model MN7000 and myMerlin™ mobile apps (Android (APP1000) and iOS (APP1001)).

The subject of this premarket notification is the integration of two new artificial intelligence (AI) algorithms utilizing machine learning (ML) techniques for the evaluation of atrial fibrillation (AF) and Pause episodes within the Assert-IQ™ ICM remote care component, Merlin.net MN7000. The goal of the AI -enabled function in Merlin.net is to reduce non-actionable clinical review burden due to false Pause and false AF episodes presented for clinician review. Specifically, this premarket submission pertains to the addition of the proposed deep neural network AI models as integrated sub-components of the Merlin.net software, MN7000, resulting in MN7000 version v2.0. There are no other proposed changes to the Assert-IQ device hardware, device firmware, device detection algorithms or other components of the system cleared in K230286.

The two new AI algorithms (CARE: Classification using AI for Rhythm Evaluation) classify AF and pause EGM episodes detected by Assert-IQ ICM devices as either true or false detection. Episodes classified as “true” will be retained in the transmission data and displayed to clinicians for review in Merlin.net web application, whereas episodes classified as “false” will be removed and not displayed to the user. These two AI algorithms, CARE-AF and CARE-Pause, are designed to significantly reduce false episodes, while maintaining true arrhythmic episodes detected by the Assert-IQ devices.

Indications for Use

There are no changes to the Indications for Use for the Assert-IQ ICM system as a result of this submission. The subject device Assert-IQ ICM system when used with the AI EGM classification system has the same indications for use as the predicate device (K230286). 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 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.

Technological Characteristics

The fundamental technology of the subject Assert-IQ™ ICM with AI algorithms (CARE-AF and CARE-Pause), relative to the predicate Assert-IQ™ ICM (K230286), is the same, as there is no change in the design, operating principle, device technology and functionality other than the addition of the AI EGM classification to the Assert-IQ remote care ecosystem.

An overview of key design/technological characteristics of the predicate Assert-IQ ICM system (K230286) and the subject Assert-IQ ICM with AI algorithms follows.

- Identical device hardware, firmware or device detection algorithms
- Identical device longevity — Assert-IQ ICM model DM5500 has a 6-year longevity, and models DM5000 and DM5300 have a 3-year longevity
- Identical remote programming capability
- Identical remote monitoring capability
- Identical 1.5T and 3T MR Conditional labeling
- Identical device telemetry via Bluetooth® Low Energy
- Addition of AI algorithms to classify AF and pause EGM episodes in the subject Assert-IQ remote care system, Merlin.net software MN7000

Substantial Equivalence

The subject Assert-IQ™ ICM system with AI algorithms is substantially equivalent to the predicate Assert-IQ™ ICM system (K230286). The Intended Use and Indications for use are not impacted by addition of the proposed AI EGM classification.

Both the subject and the predicate device (K230286) systems have the same fundamental functionality and technological characteristics. The integration of the AI algorithms into the Assert-IQ system as sub-components of MN7000 does not raise different questions of safety and effectiveness.

Differences between the subject and predicate devices have been evaluated through design verification and validation testing to provide evidence that the subject device is substantially equivalent to the predicate device. The Assert-IQ™ ICM system when used with the AI algorithms for EGM classification is substantially equivalent to the predicate Assert-IQ ICM system (K230286) based on comparisons of indications for use, operating principle, device technology, functionality, and safety.

Table 1: Substantial Equivalence

	Predicate Device Assert-IQ™ ICM System (K230286)	Subject Device Assert-IQ™ ICM System with AI algorithms
Intended Use	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 by detecting arrhythmias and transmitting data for review.	Identical; Substantially equivalent
Indications for 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.	Identical; Substantially equivalent

	Predicate Device Assert-IQ™ ICM System (K230286)	Subject Device Assert-IQ™ ICM System with AI algorithms
Device Hardware	A titanium can and elasthane header; can encapsulates a lithium carbon monofluoride battery and hardware circuitry; Bluetooth antenna	Identical; Substantially equivalent
MR Conditional	1.5T & 3T	Identical; Substantially equivalent
Remote Monitoring Method	Bluetooth low energy from ICM to myMerlin mobile app. Cellular or Wi-Fi to Merlin.net via myMerlin Mobile App	Identical; Substantially equivalent
Diagnostics	EGM collection; AF burden Trend, Activity Trends; PVC Burden Trends	Identical; Substantially equivalent
Remote Programming	Available	Identical; Substantially equivalent
EGM Classification Algorithms	AF and Pause discriminators present in the Assert-IQ device firmware	Addition of AI algorithms to classify AF and Pause EGM episodes post-device detection Substantially Equivalent The additional AI algorithms for AF and Pause EGM classification in the Assert-IQ remote care system on top of the existing EGM classification in the device firmware does not raise different questions of safety and effectiveness and the performance of the subject device has been demonstrated to be substantially equivalent to the predicate device.

Summary of Non-Clinical Performance Data

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

- Design Verification: Software Verification and System Verification, including cybersecurity testing were completed to ensure the design output meets specifications outlined in the design inputs and cybersecurity requirements. The Assert-IQ™ ICM remote care system with integration of the AI/ML algorithms, meets the functionality per the requirements and all test executions resulted in a status of Passed.
- Design Validation:
 - AI Algorithm Performance validation testing was completed to ensure the algorithms were able to properly modify AF and Pause alerts based on AI

algorithms classification outputs on the AF and Pause EGM episodes. All results met or exceeded the acceptance criteria.

AI algorithm performance assessment data

The CARE-AF and CARE-Pause algorithms are designed to reduce false episodes while maintaining a majority of true episodes. Relative sensitivity and false positive reduction (i.e. relative specificity) were used to quantify the performance of these algorithms relative to the predicate Assert-IQ™ ICM system (K230286) in a retrospective observational cohort study, where the device was used in a representative, unseen, randomly selected, intended use population.

The study included randomly selected patients who received Assert-IQ ICM for any reason for monitoring and had AF or Pause detection over 30 days of remote monitoring post device implant. Patients whose ICM data have been utilized in algorithm training and preliminary performance evaluation were completely excluded from this study. To minimize the risk of bias caused by frequent similar episodes, a maximum of two episodes were randomly selected from each patient during the available monitoring period.

The overall system performance of Assert IQ with CARE-AF is assessed using data collected from the Assert-IQ post-market study (NCT06172699) comparing device detection against a Holter monitor.

CARE-Pause algorithm performance assessment results

The CARE-Pause algorithm performance assessment was performed on 1498 Assert-IQ ICM patients from 504 clinics across the United States. Syncope was the reason for monitoring provided for 33.2% of the patients (498 out of 1498). The study endpoints of relative sensitivity and false positive reduction were met with the AI Pause algorithm independently achieving an episode-based relative sensitivity of 99.2% and a false positive reduction of 90.6%; and the overall system performance of Assert-IQ ICM with CARE-Pause achieving an episode-based sensitivity of 98.2% and episode-based positive predictive value of 78.6% with 100% patient sensitivity and no delay in diagnosis. Furthermore, the performance of this algorithm is consistent across patient subgroups stratified by gender, age, US region, and reasons for monitoring.

CARE-AF algorithm performance assessment results

The CARE-AF algorithm performance assessment was performed on 911 Assert-IQ ICM patients from 360 clinics across the United States. AF Management, Cryptogenic Stroke, Post AF Ablation and Suspected AF were the reasons for monitoring provided for 64.5% (588 out of 911) of the patients. The study endpoints of relative sensitivity and false positive reduction were met, with the AI AF algorithm independently achieving an episode-based relative sensitivity of

97.3% and a false positive reduction of 81.0%. Furthermore, the performance of this algorithm is consistent across patient subgroups stratified by gender, age, US region, and reasons for monitoring.

The Assert-IQ prospective, multicenter post-market study (NCT06172699) enrolled 151 patients with symptomatic, drug-refractory paroxysmal or persistent AF to compare Assert-IQ ICM AF detection against Holter assessment (up to 7 days per patient). Among 135 patients with analyzable data, the overall system performance of Assert IQ with CARE-AF achieved an episode-based sensitivity of 99.4% and a positive predictive value of 93.6% with 100% patient sensitivity and no delay in diagnosis.

- System validation testing was completed to demonstrate the conformance of the system to the user needs in scope. Expert users performed clinical workflows based on simulated scenarios with a representative end-to-end system. This validation effort confirms clinical workflows remain practicable and that user needs within scope are conformed to.
- Human Factors Engineering (HFE) testing identifies and mitigates potential use-related risks, thereby minimizing user errors and enhancing overall device usability and safety. This testing successfully concluded that the Assert-IQ™ ICM remote care system with integration of the AI/ML algorithms is safe and effective for its intended users, uses, and use environments.

➤ **Conclusion**

All verification and validation activities were successfully completed and did not raise new safety or performance issues; the Assert-IQ™ ICM system with integration of the AI algorithms has been demonstrated to be substantially equivalent to the predicate Assert-IQ™ ICM System (K230286).