July 2, 2026

Implicity, Inc.
Caroline Florequin
Head of Quality and Regulatory Affairs
185 Alewife Brook Pkwy., Suite 210
Cambridge, Massachusetts 02138

Re: K253463
Trade/Device Name: ILR ECG Analyzer (IM007)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: June 3, 2026
Received: June 3, 2026

Dear Caroline Florequin:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

KIMBERLY N. CROWLEY -S

For: Jennifer 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)*
K253463

Device Name
ILR ECG Analyzer (IM007)

Indications for Use *(Describe)*
IM007 is intended for use by qualified healthcare professionals for the assessment of arrhythmias in Insertable Cardiac Monitor (ICM) ECG data.
IM007 supports analyzing data recorded in compatible formats from ICMs.

This version of IM007 supports ECG data from compatible Abbott, Biotronik, Boston Scientific and Medtronic ICMs.

The device is intended for use in adult patients (18 years and older) who have been implanted with a compatible ICM for diagnosis or monitoring of cardiac arrhythmias.

IM007 is intended to be electronically interfaced with other computer systems (remote monitoring platform) that supply the ECG data to IM007 and receive the output of IM007 (analysis) for viewing by the healthcare professionals.

IM007 provides ECG signal analysis to differentiate normal rhythm from abnormalities.

IM007 is not for use in life-supporting or life-sustaining systems or ECG monitors and alarm devices.

IM007 interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and healthcare professionals on an advisory basis only, in conjunction with the clinical knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

1. Submitter

Applicant

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Date prepared: June 30th 2026
510(k) number: K253463

2. Subject Device

Trade Name	IM007 ILR ECG Analyzer, Version 2
Common Name	ILR ECG Analyzer
Manufacturer	Implicity
Classification	21 CFR 870.1425 - Programmable diagnostic computer, Class II 21 CFR 870.2340 Electrocardiograph, Class II
Product Code	DQK, DPS

3. Predicate Device

Trade Name	IM007 ILR ECG Analyzer, Version 1

Common Name	ICM ECG Analyzer
Manufacturer	Implicity
Classification	21 CFR 870.1425 - Programmable diagnostic computer, Class II 21 CFR 870.2340 Electrocardiograph, Class II
Product Code	DQK, DPS

4. Device Description

ILR ECG ANALYZER is a software medical device for the analysis of ECG signals from Insertable Cardiac Monitors (ICM) devices. It confirms the presence or absence of arrhythmias. When it is interfaced with the compatible Remote Monitoring Platform, ILR ECG ANALYZER provides additional data to healthcare professionals to support their analysis of abnormal episodes detected by ICM devices.

As with ICM data, information about the cardiac rhythm may help to determine if patient symptoms are related to arrhythmias, or to detect asymptomatic arrhythmias. Continuous and long-term cardiac monitoring may help to make informed decisions about the patient's need for medication, cardioversion, or other rate or rhythm control therapy.

ILR ECG ANALYZER receives as input an ECG data signal via the remote monitoring platform, then processes the signal with a proprietary algorithm designed to detect arrhythmias and generates the analysis results as output to the remote monitoring platform. The output label from ILR ECG ANALYZER is combined with the original ICM data including the ECG, and the ICM interpretation of the signal. ILR ECG ANALYZER is designed to improve both the sensitivity and specificity in the interpretation of device-detected ECG abnormalities. In particular, it is designed to reduce the rate of false positive (FP) events from ICM devices.

ILR ECG ANALYZER comprises of the following components:

- An algorithm (the Algorithm) that analyzes ECG files in order to detect cardiac rhythm abnormalities.
- A communication interface to external applications (compatible platforms) for the Algorithm and the processing of ECG files. The Application Programming Interface (API) consists of two messaging queues (one for input and one for output).

ILR ECG ANALYZER works as follows:

- ILR ECG ANALYZER receives input data (an ECG file and device parameters) from the Remote Monitoring Platform using the input queue
- The file is processed by the Algorithm which delineates zones with abnormal waveforms (ECG signals not defined as normal sinus rhythm). The output format is a descriptive label of the ECG episode analyzed.
- ILR ECG ANALYZER sends a response to the Remote Monitoring Platform using the output queue.

5. Indication for Use

Indication for use/Intended use

IM007 is intended for use by qualified healthcare professionals for the assessment of arrhythmias in

Insertable Cardiac Monitor (ICM) ECG data.
IM007 supports analyzing data recorded in compatible formats from ICMs.
This version of IM007 supports ECG data from compatible Abbott, Biotronik, Boston Scientific and Medtronic ICMs. The device is intended for use in adult patients (18 years and older) who have been implanted with a compatible ICM for diagnosis or monitoring of cardiac arrhythmias.
IM007 is intended to be electronically interfaced with other computer systems (remote monitoring platform) that supply the ECG data to IM007 and receive the output of IM007 (analysis) for viewing by the healthcare professionals.
IM007 provides ECG signal analysis to differentiate normal rhythm from abnormalities.
IM007 is not for use in life-supporting or life-sustaining systems or ECG monitors and alarm devices.
IM007 interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and healthcare professionals on an advisory basis only, in conjunction with the clinical knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

Target population
IM007 receives data from ambulatory ICM devices. The patient population is therefore an ambulatory ECG population, including patients implanted with ICMs as determined by the indication for use of the ICM (in particular detection of atrial fibrillation, and ventricular tachycardia or asystole causing syncope).
IM007 is intended to be used on data from patients aged eighteen and over.

6. Technological Characteristics

IM007 V2 and Predicate Device have substantially equivalent fundamental scientific technology. Both consist of:

- An algorithm based on Machine Learning technology.
- An API to access to the algorithm (cloud-based service system)

The subject device has no client-side application website but is designed to be interfaced with a compatible remote monitoring platform which has a client-side web interface.

7. Summary of Characteristics and Substantial equivalence

	Subject Device	Predicate Device	Comparison to Predicate Device
Device Name	ILR ECG Analyzer (IM007) V2	ILR ECG Analyzer (IM007) V1	Same device
Manufacturer	IMPLICITY INC	IMPLICITY INC	Same
510(k) #		K210543	NA
Regulation Number	21 CFR 870.1425 21 CFR 870.2340	21 CFR 870.1425 21 CFR 870.2340	Same
Class	II	II	Same
Device Class / Name	Electrocardiograph	Electrocardiograph	Same
Product Code	DQK, DPS	DQK, DPS	Same
Product Code Device Definition	An electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart.	An electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart.	Same
Software Level of Concern / Documentation Level	Enhanced	Major	Same

Indication for Use comparison			
	Subject Device (IM007 V2)	Predicate Device (IM007 V1)	Comparison to Predicate Device

Indication for Use/Intended Use	IM007 is intended for use by qualified healthcare professionals for the assessment of arrhythmias in Insertable Cardiac Monitor (ICM) ECG data. IM007 supports analyzing data recorded in compatible formats from ICMs. This version of IM007 supports ECG data from compatible Abbott, Biotronik, Boston Scientific and Medtronic ICMs. The device is intended for use in adult patients (18 years and older) who have been implanted with a compatible ICM for diagnosis or monitoring of cardiac arrhythmias. IM007 is intended to be electronically interfaced with other computer systems (remote monitoring platform) that supply the ECG data to IM007 and receive the output of IM007 (analysis) for viewing by the healthcare professionals. IM007 provides ECG signal analysis to differentiate normal rhythm from abnormalities. IM007 is not for use in life-supporting or life-sustaining systems or ECG monitors and alarm devices. IM007 interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and healthcare professionals on an advisory basis only, in conjunction with the clinical knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.	IM007 is intended for use by qualified healthcare professionals for the assessment of arrhythmias in Insertable Cardiac Monitor (ICM) ECG data. IM007 supports downloading and analyzing data recorded in compatible formats from ICMs. This version of the IM007 only supports ECG data from Medtronic ICMs. IM007 is intended to be electronically interfaced with other computer systems (remote monitoring platform) that supply the ECG data to IM007 and receive the output of IM007 (analysis) for viewing by the healthcare professionals. IM007 provides ECG signal processing and analysis, to detect asystole, bradycardia, atrial tachycardia or atrial fibrillation, ventricular tachycardia, normal rhythm and artifact. IM007 is not for use in life supporting or sustaining systems or ECG monitors and Alarm devices. IM007 interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.	Same target users (HCP). Same type of input data (ICM data) but the V2 supports more ICM models. Same interface The output of the subject device is similar to the predicate device output, The V2 output is a simplified version of V1 output. Both devices are not intended to be use in life supporting or sustaining systems or ECG monitors and alarm devices and not intended to be the sole means of diagnosis.

Patient population	IM007 receives data from ambulatory ICM devices. The patient population is therefore an ambulatory ECG population, including patients implanted with ICMs as determined by the indication for use of the ICM (in particular detection of atrial fibrillation, and ventricular tachycardia or asystole causing syncope). IM007 is intended to be used on data from patients aged eighteen and over.	IM007 receives data from ambulatory ICM devices. The patient population is therefore an ambulatory ECG population, including patients implanted with ICMs as determined by the indication for use of the ICM (in particular detection of atrial fibrillation, and ventricular tachycardia or asystole causing syncope). IM007 is intended to be used on data from patients aged eighteen and over.	Same patient population
Technological features			
	Subject Device (IM007 V2)	Predicate Device (IM007 V1)	Comparison to Predicate Device
Heart rate determination for non-paced adult	Yes	Yes	Same
QRS detection	Yes. This is not an output of the subject device but is calculated as an intermediate value prior to generating the output.	Yes. This is not an output of the predicate device but is calculated as an intermediate value prior to generating the output.	Same
Non-paced arrhythmia interpretation for adult patients	Yes	Yes	Same
User interface	No IM007 does not include a user interface for viewing ECG data, as the viewing of ECG data belongs to the “client application”.	No IM007 does not include a user interface for viewing ECG data, as the viewing of ECG data belongs to the “client application”.	Same
Database to store the results	Yes IM007 stores results in the “client application”.	Yes IM007 stores results in the “client application”.	Same
Technology			
Feature	Subject Device (IM007 V2)	Predicate Device (IM007 V1)	Comparison to Predicate Device
Deployment	Cloud based and interfaced with the Remote Monitoring Platform	Cloud based and interfaced with the Remote Monitoring Platform	Same
Input data type	Raw ECG signal Meta-data (device manufacturer, device type and	Raw ECG signal Meta-data (device model and device settings)	Similar Same input data type But V2 supports more

	device settings) Manufacturer of compatible ICM devices: Medtronic, Abbott, Biotronik, Boston Scientific (some having manufacturer-proprietary AI pre-filtering algorithm)	 Manufacturer of compatible devices: Medtronic models without AI pre-filtering algorithm	ICM models.
Machine Learning Methodology	ML classification algorithm	ML classification algorithm	Same
Device Output	Classification of the episode - Normal Rhythm or no sustained arrhythmia - Suspected abnormality / Artifact	Classification of the episode - Global label - Cardiac rhythm abnormalities (Asystole, Bradycardia, AT/AF, VT, Artifact, Normal Rhythm, Unspecified abnormality)	Similar The output of subjected device is similar to the predicate device output, The V2 output is a simplified version of V1 output.

The Implicity IM007 V2 (subject device) has the same intended use compared to the predicate device. Both the subject and predicate device are software algorithms constructed using machine learning technology to help HCP assess the ECG from ICM. Differences in number of compatible models between the subject and the predicate device do not pose different questions of safety or effectiveness for the subject device.

A clinical evaluation was conducted to assess the performance of the subject device (IM007 V2) compared to the predicate device (IM007 V1). We showed that the Implicity IM007 V2 algorithm is substantially equivalent for ICM devices to the predicate device.

Therefore, the Implicity IM007 V2 algorithm is substantially equivalent to the predicate IM007 V1 (K210543).

8. Non-clinical Performance

Non-clinical testing was conducted to assess algorithm performance and to verify that IM007 Version 2 performs as intended.

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device included a Documentation Level of Enhanced. Testing was conducted to demonstrate that the IM007 Version 2 algorithm works as designed.

Algorithm performance testing was assessed using ECG databases from the ANSI/AAMI EC57:2012 standard as well as Implicity proprietary databases. The results of the testing demonstrate that IM007 V2 performs to its specifications and meets its intended use, which is substantially equivalent to that of the predicate device. A traditional prospective clinical study was not required.

8.1. Performance based on databases ANSI / AAMI EC57:2012

As IM007 performs cardiac rhythm analysis, it is evaluated following the American standard:
ANSI / AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms

Following these standard requirements, the following databases are used as the evaluation databases:

- The MIT-BIH database: The Massachusetts Institute of Technology–Beth Israel Hospital Arrhythmia Database (48 records of 30 minutes each),
- The CU database: The Creighton University Sustained Ventricular Arrhythmia Database (35 records of 8 minutes each—supplied with the MIT–BIH database with incomplete annotations),
- The NST database: The Noise Stress Test Database (12 ECG records of 30 minutes each plus 3 records of noise only— supplied with the MIT–BIH database),
- The AHA database: The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors (80 records of 35 minutes each)

8.2. Performance based on Implicity proprietary database

Two cohorts are constituted from the overall study cohort:

- the “development” cohort, used to train the algorithm and measure the performance of the IM007 algorithm during the development phase.
- the “clinical validation” cohort, used to validate clinically the final version of the algorithm to be presented to the FDA, to prevent any overfitting or avoidable bias in the evaluation.

The development dataset is defined as all ICM devices followed by medical centers using Implicity as their remote monitoring platform and were collected from 2019-06 to 2025-08 during IM007 training and validation phase. This includes 1478 devices, from which 5551 episodes were collected.

These episodes are selected to have the most variability available in terms of variety of devices and device episode types (the episode types identified by the device that recorded the episode). These episodes were used as a development dataset (for training and analytical validation).

The retrospective clinical evaluation dataset was collected on 2020-11 for the devices already compatible with IM007 V1 and from 2024-11 to 2025-08 for the devices not compatible with IM007 V1, from European and American medical centers that were not included in the development dataset, ensuring no overlap between datasets in terms of patient, device or medical center.

8.2.1. Primary endpoints

Following the results of the prospective study IMCAP-AI (Crespin et al. 2024) based on the previous version of IM007, the primary performance objectives were defined such as:

- Sensitivity ≥ 92%
- Specificity: considering the presence of a manufacturer proprietary AI algorithm for a subset of the ICMs, this objective was stratified based on the presence of manufacturer-proprietary AI algorithms:
    - Specificity ≥ 72%: for episodes of ICM devices that do not feature a manufacturer-proprietary AI pre-filtering algorithm.
    - Specificity ≥ 50%: for episodes of ICM devices that do feature a manufacturer-proprietary AI pre-filtering algorithm.

The secondary objective is defined such as:

- Artifact Sensitivity ≥ 65%:

The primary endpoints of the clinical evaluation were defined as following: for each objective, the lower bound of the 95% confidence interval of the performance within each respective subgroup must meet or exceed the specified threshold to demonstrate required performance ensuring that the effect of the previous algorithm is preserved with this new version.

In addition to the primary endpoints, secondary endpoints were established to assess the robustness and generalizability of the IM007 V2 algorithm's performance across when stratified by ICM Manufacturer (Abbott, Biotronik, Boston Scientific, Medtronic) to demonstrate that the algorithm is device-agnostic and provides a consistent, high level of performance regardless of the underlying ICM manufacturer. For the secondary endpoints to be met, the calculated performance for each metric (Sensitivity, Specificity, Artifact Sensitivity) within each of the nested subgroups (e.g. patients implanted with a Biotronik ICM without AI pre-filtering algorithm) must meet or exceed the established performance thresholds.

8.2.2. Dataset statistical analysis

Demographic Variable	Development dataset	Pre-market Clinical evaluation dataset
Nb medical centers	60	70
Nb patients	1,465	1,710
Nb devices	1,478	1,713
Nb episodes	5,551	2,659

# Nb episodes with abnormalities *(including VT, AT/AF, Asystole, Bradycardia and Artifact)*	2,203	1,494
Nb episodes with Artifact	466	570
Mean age ± SD (years)	64.9 ± 16.4	67.5 ± 15.0
Gender		
% Male	41.8	27.0
% Female	32.1	25.3
% Unknown	26.1	47.7
Region		
% EU	86.1	37.8
% US	13.9	62.2
Manufacturer device model		
% Abbott	9.8	18.0
% Biotronik	14.7	22.4
% Boston Scientific	11.6	15.8
% Medtronic	63.9	43.8

8.2.3. Global Performance

The following table presents the performance for ICMs with and without manufacturer proprietary AI algorithm, for the datasets Analytical validation performance and pre-market clinical evaluation.

Cohort	performance metric	Analytical validation performance	Pre-market clinical evaluation	Pre-defined objective *(for lower bound CI)*	Status
ICMs **with** manufacturer proprietary AI algorithm provided	Sensitivity	97.0% [96.6; 97.5]	98.3% [94.9; 99.4]	≥ 92%	PASSED
	Specificity	65.4% [63.6; 67.2]	61.6% [54.1; 69.2]	≥ 50%	PASSED
	Artifact Detection	100.0%	87.8% [81.7 - 92.4]	≥ 65%	PASSED
ICMs **without** manufacturer proprietary AI algorithm provided	Sensitivity	93.8% [93.2; 94.3]	94.3% [92.4; 95.7]	≥ 92%	PASSED
	Specificity	72.7% [72.0; 73.3]	75.6% [72.8; 78.1]	≥ 72%	PASSED
	Artifact Detection	81.0% [79.8; 82.2]	73.3% [68.8 - 77.4]	≥ 65%	PASSED

In conclusion, all the primary endpoints are met on both the analytical validation and the clinical evaluation study.

8.2.4. Performance by manufacturer

Clinical evaluation performance stratified by manufacturer for the subgroup of ICMs **with** AI pre-filtering algorithm:

Performance metric	ICMs with AI pre-filtering algorithm	
	Boston Scientific	Medtronic
Sensitivity	100%	98.2%
Specificity	62.5%	61.4%
Artifact Detection	92.9%	87.2%

Clinical evaluation performance stratified by manufacturer for the subgroup of ICMs **without** AI pre-filtering algorithm:

Performance metric	ICMs without AI pre-filtering algorithm			
	Abbott	Biotronik	Boston Scientific	Medtronic
Sensitivity	96.9%	94.8%	93.8%	93.1%
Specificity	78.9%	72.4%	79.4%	72.3%
Artifact Detection	73.3%	66.7%	74.8%	77.6%

The IM007 V2 algorithm successfully met all pre-defined global performance objectives for every manufacturer tested across both subgroups. This demonstrates the algorithm's robust design and its ability to deliver reliable performance across a diverse hardware ecosystem. In conclusion, all the secondary endpoints of this stratified clinical evaluation study are met.

Additional subgroup analysis was also conducted to demonstrate performance was substantially equivalence across the intended use population and for the specific compatible ICM models. Additional analysis of the primary endpoints when incorporating Artifact episodes was also provided to support substantially equivalent performance.

9. Conclusion

The results of non-clinical testing demonstrate that IM007 V2 meets its intended use which is equivalent to that of the predicate device. Testing also ensured that IM007 V2 performs as intended and does not raise different questions of safety or effectiveness as compared to the predicate device.