November 3, 2021

Implicity, Inc.
℅ Mark Johnson
Regulatory Consultant
MJ Medtech Consulting Services LLC
24125 Butteville Rd. NE
Aurora, Oregon 97002

Re: K210543
Trade/Device Name: IM007
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: October 1, 2021
Received: October 4, 2021

Dear Mark Johnson:

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,

Jennifer Shih 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)*
K210543

Device Name
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 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 monitor 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.

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) substantial equivalence information is submitted in accordance with the requirements of 21 CFR 807.92

1 General Information

Applicant	IMPLICITY INC 185 ALEWIFE BROOK PARKWAY - SUITE 210 CAMBRIDGE, MA 02138 USA Phone: +33 6 76 731 731
Contact Person	David Perlmutter Head of R&D IMPLICITY INC 185 ALEWIFE BROOK PARKWAY - SUITE 210 CAMBRIDGE, MA 02138 USA regulatory@implicity.com Phone: +33 6 76 731 731
Assisted by	Mark Johnson Regulatory consultant to Implicity Inc MJ Medtech Consulting Services LLC 3332 Rockwood circle Billings, Montana 59102 +1 (503) 575-5886

2 Date prepared: November 2, 2021

3 Device Information

Trade Name	IM007 Insertable Cardiac Monitor ECG Analysis System
Common Name	ICM ECG Analysis System
Classification	21 CFR 870.1425, Programmable diagnostic computer, Class II 21 CFR 870.2340, Electrocardiograph, Class II
Product Code	DQK, DPS

4 Predicate Device

The predicate and reference devices for IM007 Insertable Cardiac Monitor ECG Analysis System are:

Predicate Device CARDIOLOGS, Inc., CardioLogs ECG Analysis Platform, K170568

Reference Device MEDTRONIC, Inc., Reveal LINQ Insertable Cardiac Monitor, K163460

Table 1 provides device information for the subject device Implicity IM007 and compares it to the predicate and the reference devices listed.

Table 1 Predicate Comparison

	Subject Device	**Predicate Device**	**Reference Device**	**Comparison to Predicate**
Device Name	IM007	CardioLogs ECG Analysis Platform	Reveal LINQ Insertable Cardiac Monitor, Model LNQ11	
Manufacturer	IMPLICITY INC	CARDIOLOGS TECHNOLOGIES	MEDTRONIC INC	
510(k) #	K210543	K170568	K163460	
Regulation Number	21 CFR 870.1425 21 CFR 870.2340	21 CFR 870.1425 21 CFR 870.2340	21 CFR 870.1025	Same
Class	II	II	II	Same
Device Class / Name	Programmable diagnostic computer, Electrocardiograph	Programmable diagnostic computer, Electrocardiograph	Detector and Alarm, Arrhythmia	Same
Product Code	DQK, DPS	DQK, DPS	DSI	Same
Level of Concern	Major	Moderate	Major	Same

The following Table 2 compares the Indication for Use of the Subject Device to the Predicate and the Reference Devices.

Table 2 Comparison between Subject, Predicate and Reference Devices indication for use

	Subject Device	**Predicate Device**	**Reference Device**	**Comparison to Predicate Device**
Indication for Use	IM007 is intended for use by qualified healthcare professionals for the assessment of arrhythmias in Insertable Cardiac Monitor (ICM) ECG data.	The CardioLogs ECG Analysis Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data.	The Reveal LINQ ICM is an insertable automatically activated and patient-activated monitoring system that records subcutaneous ECG. It is indicated in the following cases: ● patients with clinical syndromes or situations at increased risk of	The Indication for Use for the Subject Device is focused on a subset of ECG data which specifically is generated from ICM devices. The algorithm has been developed for use with all ECG generating cardiac monitors. Validation of Implicity's first generation system is focused on ICM outputs. The safety and performance of ECG interpretation of ICM devices is comparable to that of the broader array of ECG systems.

Table 2 Comparison between Subject, Predicate and Reference Devices indication for use				
	Subject Device	**Predicate Device**	**Reference Device**	**Comparison to Predicate Device**
	IM007 supports downloading and analyzing data recorded in compatible formats from ICMs. This version of the IM007 only supports ECG data from Medtronic ICMs.	The product supports downloading and analyzing data recorded in compatible formats from any device used for the arrhythmia diagnostics such as Holter, event recorder, 12 lead ambulatory ECG devices, or other similar devices when assessment of the rhythm is necessary.	cardiac arrhythmias ● patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia. The device has not been tested specifically for pediatric use.	The Subject Device takes ECG data only from ICMs, and as in the Predicate, use is restricted to compatible formats.
	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.	The Cardiologs ECG Analysis Platform can also be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system. The product can be integrated into computerized ECG monitoring devices.		Same

Table 2 Comparison between Subject, Predicate and Reference Devices indication for use				
	Subject Device	**Predicate Device**	**Reference Device**	**Comparison to Predicate Device**
	IM007 provides ECG signal processing and analysis, to detect asystole, bradycardia, atrial tachycardia or atrial fibrillation, ventricular tachycardia, normal rhythm and artifact.	The Cardiologs ECG Analysis Platform provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis.		The Subject Device uses equivalent signal processing and analysis methodology as the Predicate. The Subject Device operates as a software module electronically interfaced to another computer system that handles ECG data, which is also one of the modes of operation of the Predicate.
	IM007 is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.	The CardioLogs ECG Analysis Platform is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.		Same

Table 2 Comparison between Subject, Predicate and Reference Devices indication for use				
	Subject Device	**Predicate Device**	**Reference Device**	**Comparison to Predicate Device**
	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.	CardioLogs ECG Analysis Platform 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

Table 2 Comparison between Subject, Predicate and Reference Devices indication for use				
	Subject Device	**Predicate Device**	**Reference Device**	**Comparison to Predicate Device**
Patient population	Adults (over 18) 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. The device has not been tested specifically for pediatric use.	Adults (over 18).	- 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 The device has not been tested specifically for pediatric use.	Same. The Subject Device has also the same target population of the Reference Device, which is a subset of the target population of the Predicate Device.

The Subject, Predicate, and Reference devices all provide output classifications in the analysis of ECG signals that are transmitted from compatible Insertable Cardiac Monitor (ICM) devices. Table 3 below compares the output classifications between these devices.

Table 3 Comparison between Subject, Reference & Predicate Devices rhythm analysis outputs			
Subject Device **Output classification**	**Reference Device** **Reveal LINQ**	**Predicate Device**	**Comparison with Predicate Device**
Asystole (Ventricular pause) Absence of ventricular contraction for a duration equal or superior to the asystole programmable duration.	**Pause** (asystole) No ventricular events are sensed for a programmable period of time.	**Ventricular pause** No ventricular complex during at least three seconds.	**Same** (except for the programmable duration)
Bradycardia Slow ventricular rate. Lower than the programmable brady rate	**Brady** (bradyarrhythmia) The patient's heart rate falls to a rate that is lower than the programmable brady threshold.	**Sinus bradycardia** (< 50 /min) Sinus rhythm with unusual or abnormal slow rate.	**Same**
AT/AF (Atrial Tachycardia / Atrial Fibrillation) At least one of the following: - Atrial tachycardia (ectopic) - Atrial flutter - Atrial fibrillation	**AF only or AT/AF** (atrial fibrillation only or atrial tachyarrhythmia/atrial fibrillation) The patient has an atrial tachyarrhythmia or atrial fibrillation. The clinician can also choose to record atrial fibrillation only. The Reveal LINQ device detects an episode of conducted AT or AF by analyzing the irregularity of ventricular rhythm using an automatic algorithm.	**AF** - Atrial fibrillation **AF** - Atrial fibrillation or flutter (uncertain) Atrial flutter Atrial tachycardia or flutter AF - Atrial fibrillation, flutter or atrial tachycardia Atrial tachycardia, ectopic AT - Atrial tachycardia -	**Same** All classifications are regrouped under one because of the clinical significance and the fact that it is often impossible to distinguish with certainty by healthcare professional.

Table 3 Comparison between Subject, Reference & Predicate Devices rhythm analysis outputs			
Subject Device **Output classification**	**Reference Device** **Reveal LINQ**	**Predicate Device**	**Comparison with Predicate Device**
		short run(s)	
VT – Ventricular Tachycardia At least one of the following: -Tachycardia that originates in a ventricle. Sometimes life-threatening. NSVT - Non-sustained ventricular tachycardia	**Tachy** (ventricular tachyarrhythmia) The patient's heart rate increases to a rate that is higher than the programmable tachy rate (interval) threshold for the programmable tachy duration or higher than 231 bpm (intervals lower than 260 ms) for 30 of the last 40 beats.	**VT** - Ventricular tachycardia Wide-QRS tachycardia that originates in a ventricle. Sometimes life-threatening. NSVT - Non-sustained ventricular tachycardia Run of ≥ 4 consecutive premature ventricular complexes with a heart rate ≥ 100 /min.	**Same** All classifications are regrouped under one because of the clinical significance and the fact that it is often impossible to distinguish with certainty by healthcare professional, with the exception of using the programmable tachy rate.
Normal Rhythm The ECG does not present any significant abnormality.	**N/A** (Normal rhythm is absence of abnormal classification). Normal rhythm is detected by the device but not transmitted through remote monitoring.	**Normal rhythm** is absence of abnormal classification.	**Same**
Unspecified abnormality An abnormality is detected in the signal, but the abnormality is	**N/A**	**N/A**	This label is specific to IM007 This output prompts the healthcare

Table 3 Comparison between Subject, Reference & Predicate Devices rhythm analysis outputs			
Subject Device **Output classification**	**Reference Device** **Reveal LINQ**	**Predicate Device**	**Comparison with Predicate Device**
not classified as one of the other abnormality labels by the algorithm.			professional to review the ECG
Artifact Presence of a non-cardiac noise, which distorts the signal and prevents proper medical interpretation of the specified portion.	**N/A**	**X** - Pure noise Tracing with only noise and no ECG data	**Same**

Table 4 provides a comparison of the features of the Subject and Predicate devices.

Table 4 Comparison between Subject and Predicate Devices features			
Feature	**Subject Device** **IM007**	**Predicate Device** **CardioLogs ECG Analysis Platform**	**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	Same
Non-paced arrhythmia interpretation for adult patients	Yes	Yes	Same

Table 4 Comparison between Subject and Predicate Devices features			
Feature	**Subject Device IM007**	**Predicate Device CardioLogs ECG Analysis Platform**	**Comparison to Predicate Device**
User interface to view ECG data with tools	No IM007 does not include a user interface for viewing ECG data, as the viewing of ECG data belongs to the "client" application.	Yes The user should only use CardioLogs' user interface to view ECG data analysis.	not necessary for the intended use
Database to store the results	No Results are stored in the "client application".	Yes	Not necessary for the intended use

Table 5 provides a comparison of the technology of the Subject, Predicate, and Reference devices

Table 5 Comparison between Subject, Reference, and Predicate Devices technology			
Subject Device	**Predicate Device**	**Reference Device**	**Comparison to Predicate Device**
The IM007 consists of a server-side service, that provides tools to process and analyze ECGs through various algorithms. IM007 receives request from client application, performs arrhythmia analysis on ECG data received and responds to client application with the output from the algorithm to be	The CardioLogs ECG Analysis Platform consists of server-side, application Platform as a Service (PaaS) cloud-based system, and a client-side application website. The server-side, application PaaS component collects, stores, performs arrhythmia analysis on ECG uploads, and transfers data to and from the client-side application.	The Reveal LINQ ICM is designed to automatically record the occurrence of an arrhythmia in a patient, continuously senses the patient's subcutaneous ECG, and analyses the timing of ventricular events to detect possible episodes of arrhythmia. The Reveal LINQ ICM adds three rules to	IM007 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). Subject device has no client-side application

Table 5 Comparison between Subject, Reference, and Predicate Devices technology			
Subject Device	**Predicate Device**	**Reference Device**	**Comparison to Predicate Device**
stored on the client application. The automated proprietary ECG algorithm provides supportive information for ECG diagnosis. The algorithm can be accessed by connecting to the IM007's Application Programming Interface.	The client-side application allows the users to review ECG, edit the analysis results produced by the server-side application PaaS component. The users may upload ECG to the ECG Analysis Platform via the API (REST web service) from any computer equipment, or, in the specific cases where the user's hardware is already connected to the CardioLogs' Application Programming Interface (API), the ECG is automatically sent to CardioLogs' servers.	reduce false positive detections listed below: 1-Atrial Algorithms – Adaptive P-sense rule 2-Dual Sense Brady rejection rule 3-Dual Sense Asystole rejection rule.	website but is designed to be interfaced with a remote monitoring platform which has a client-side web interface.

5 Device Description

IM007 is a software medical device for the analysis of ECG signals from Insertable Cardiac Monitor (ICM) devices and confirms the presence or absence of arrhythmias. When it is interfaced with a compatible remote monitoring platform, IM007 provides additional data to healthcare professionals to support the analysis of abnormal episodes detected by ICM devices.

IM007 receives as input an ECG data signal via the Implicity remote monitoring platform, then processes the signal with a proprietary algorithm designed to detect arrhythmias and generates as output the result of the analysis to a remote monitoring platform.

IM007 comprises:

- An algorithm (the Algorithm) that analyzes ECG files in order to detect cardiac rhythm abnormalities.
- A communication interface to external applications with the Algorithm and processing of ECG

files. The API consists of 2 messaging queues (an input and an output).

IM007 works as follows:

- IM007 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 sequence of waveform labels/start time/end time.
- IM007 sends a response to the Remote Monitoring Platform using the output queue.

6 Intended Use

The predicate and subject device have the same intended use. Both devices are intended for use by qualified healthcare professionals for the assessment of arrhythmias in ECG data. The Indication for Use for the Subject Device is focused on a subset of ECG data which specifically is generated from compatible ICM devices.

The indication for use of IM007 is as follows:

> 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 monitor 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.

7 Technological Characteristics

IM007 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.

8 Non-clinical Performance

Non-clinical testing was conducted to assess algorithm performance and to verify that IM007 performs as intended. 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 performs to its specifications and meets its intended use, which is substantially equivalent to that of the predicate device.

9 Conclusion

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