May 2, 2025

ATsens Co., Ltd.
% Do Hyun Kim
CEO
BT Solutions, Inc.
Unit 303, 337, Gonghang-daero, Gangseo-gu
Seoul 07590
South Korea

Re: K242583
Trade/Device Name: AT-Patch (ATP-C130/ATP-C70)
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, DQK, MLO
Dated: April 3, 2025
Received: April 4, 2025

Dear Do Hyun Kim:

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,

Jennifer W. Shih -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242583

Device Name
AT-Patch (ATP-C130, ATP-C70)

Indications for Use *(Describe)*
The device is intended to measure, analyze, edit and report continuous electrocardiogram (ECG) information for long-term recording (ATP-C130: up to 14 days, ATP-C70: up to 7 days) by attaching to the patient's torso. ECG records are saved in the device during use and are not intended for real-time monitoring. After the wear period is completed, the ECG data is transmitted to the AT-Report. A primary analysis is performed by the algorithms within the AT-Report, and then a physician report is issued based on those results after a secondary analysis by a clinician or trained operator with experience in ECG analysis to correct any incorrectly detected events. The Physician report is offered to clinicians or physicians on an advisory basis only. The device is used by patients as prescribed by physicians or medical personnel. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, fatigue, or anxiety.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Preparation Date: April 29, 2025

1. Applicant / Submitter

Applicant/Submitter: ATsens Co., Ltd. / KeonHoon Lee
Address: Point Town 803, 11, Gumi-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13637 Republic of Korea
Tel: +82-70-5220-0738
Fax: +82-70-8270-0738
Email: khlee@atsens.com

2. Submission Contact Person

Contact Person: Do Hyun Kim, BT Solutions, Inc.
Address: 904, Eonju-ro 86-gil 5, Gangnam-gu, Seoul, 06210, Republic of Korea Tel: +82-2-538-9140
Tel: +82-2-538-9140
Fax: +82-2-539-9140
Email: ceo@btsolutions.co.kr

3. Device Information

Trade Name	AT-Patch
Common Name	AT-Patch
Classification Name	Medical magnetic Tape Recorder Programmable diagnostic computer
Classification Regulation	21CFR870.2800 21CFR870.1425
Device Class	2
Product Code	DSH, DQK, MLO

4. Predicate Device Information

4.1 Predicate device 1 (K203638)

Manufacturer	ATsens Co., Ltd.
Device Name	AT-Patch ECG Analysis System
510(k) number	K203638

4.2 Predicate device 2 (K162023)

Manufacturer	GETEMED Medizin-und informationstechnik AG
Device Name	CardioDay V2.5
510(k) number	K162023

5. Description

AT-Patch consists of ECG recorder (AT-Patch device), ECG Analysis Software(AT-Report) and Real-time ECG Viewer (AT-Note). ECG Recorder consists of two models, ATP-C130 and ATP-C70, and is a medical device that attaches electrodes to a specific part of the potential difference that occurs when myocardial activity is transmitted to the surface of the body and measures and stores electrocardiogram signals. (ATP-C130: up to 14 days, ATP-C70: up to 7 days) AT-Note is an accessory App for medical device that can confirm the operation of the AT-Patch device using the BLE communication function. AT-Report is a medical device software that receives data stored in AT-Patch device using a Dedicated USB Cable and analyses it to provide information which is used to take decisions with diagnosis and can confirm the operation of AT-Patch device using the BLE communication function. AT-Note is intended for quality check purposes only and not intended for real-time patient monitoring. ECG analysis is performed only after data collection is completed.

6. Technological Characteristic

Product Name: AT-Patch		
	Item	**Description**
ECG	**Type**	BF type
	Sampling Rate	250 sample/sec
	Input Offset Dynamic Range	±300mV
	Channel	1 channel
	ADC Resolution	10 bits
	Input Impedance	>10MΩ
	Frequency Response	0.67Hz to 40Hz
	Heart rate range	30 ~ 250 bpm
Electrode	**AC impedance**	Less than 3KΩ (10Hz)
RF	**RF communication**	2.4GHz BLE
	BLE specification	IEEE 802.15.4

	Effective Radiated Power	<1mW
	RF Frequency Band of TX	2.4GHz
	Bandwidth of the Receiver	2400 ~ 2480MHz
S/W	**CPU**	ARM Cortex-M4
	Supported App	Android 10.0 or higher iOS 15.8.1 or higher
	Supported AT-Report Version	Window 10 (64bit) or window 11 (64bit)
Power Requirement	**Power Supply**	DC 3V, Coin Battery (CR2032)
	Intended use period	ATP-C130: Up to 14 days ATP-C70: Up to 7 days
Physical Characteristics	**Total Size (L x W x H: mm)**	ATP-C130: 84 x 48.8 x 8.5 ATP-C70: 74 x 47.1 x 8.4
	Sub Patch Size (L x W x H: mm)	ATP-C130: 104 x 68.8 x 0.05 ATP-C70: 95 x 68.1 x 0.05
	Tape Patch Size (L x W x H: mm)	123 x 87.84 x 0.05
	Main Body Size L x W x H: mm)	ATP-C130: 39 x 31 x 7.8 ATP-C70: 39.6 x 32.6 x 7.7
	Weight (g)	Main Body: Below 13g
	Lifetime	12 months

7. Intended Use / Indication for use

7.1 Indications for Use

The device is intended to measure, analyze, edit and report continuous electrocardiogram (ECG) information for long-term recording (ATP-C130: up to 14 days, ATP-C70: up to 7 days) by attaching to the patient's torso. ECG records are saved in the device during use and are not intended for real-time monitoring. After the wear period is completed, the ECG data is transmitted to the AT-Report. A primary analysis is performed by the algorithms within the AT-Report, and then a physician report is issued based on those results after a secondary analysis by a clinician or trained operator with experience in ECG analysis to correct any incorrectly detected events. The Physician report is offered to clinicians or physicians on an advisory basis only. The device is used by patients as prescribed by physicians or medical personnel. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, fatigue, or anxiety.

7.2 Target treatment group

1) Patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, presyncope, syncope, fatigue, or

anxiety.
2) Patients with heart disease such as arrhythmia

7.3 Target User

1) The patients (Device, AT-Note app & Tape Patch)
2) Trained ECG technician or clinician (Device, AT-Note app, Sub-Patch & AT-Report).

8. Substantial Equivalence Discussion

Device & App of AT-Patch is substantially equivalent to the predicate device by ATsens Co., Ltd. The following comparison table is presented to demonstrate substantial equivalence.

A. Comparison with predicate device (Device & App)

Descriptive Information	Subject Device	Predicate Device 1	S.E.
Manufacturer	ATsens Co., Ltd.	ATsens Co., Ltd.	Yes
Device Name	AT-Patch (Device) AT-Note (App)	AT-Patch (Device) AT-Note (App)	Yes
510(k) number	K242583	K203638	No
Classification Product Code / Regulatory Number	DSH (21CFR§870.2800)	DSH (21CFR§870.2800)	Yes
Regulatory Class	2	2	Yes
Use environment	1. Attaching & Connecting device: Hospital or clinic 2. ECG measurement & using device: Home-healthcare	1. Attaching & Connecting device: Hospital or clinic 2. ECG measurement & using device: Home-healthcare	Yes
Indications for Use	The device is intended to measure, analyze, edit and report continuous electrocardiogram (ECG) information for long-term recording (ATP-C130: up to 14 days, ATP-C70: up to 7 days) by attaching to the patient's torso. ECG records are saved in the device during use and are not intended for real-time monitoring. After the wear period is completed, the ECG data is transmitted to the AT-Report. A primary analysis is performed by the algorithms within t	The device is intended to measure, save, and view continuous electrocardiogram (ECG) information for long-term recording (up to 14 days) from ambulatory patients by attaching to the skin surface. ECG records are stored in the device for review after the recording period (up to 14 days) is completed, and are not intended for real-time monitoring. The device does not include automated ECG analysis functions, and the recorded ECGs are not intended for automated	Yes

	he AT-Report, and then a physician report is issued based on those results after a secondary analysis by a clinician or trained operator with experience in ECG analysis to correct any incorrectly detected events. The Physician report is offered to clinicians or physicians on an advisory basis only. The device is used by patients as prescribed by physicians or medical personnel. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, fatigue, or anxiety.	analysis. The device allows patient and clinicians to view the ECG signal recorded in real- time solely for the purpose of visual assessment of the recording quality; the ECG signal displayed in real time is not intended for any clinical or diagnostic use. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, fatigue, or anxiety.	
Prescription or OTC	Prescription	Prescription	Yes
Technological characteristics			
Key system components	1) Device (ATP-C130, ATP-C70) 2) App	1) Device (ATP-C130) 2) App	Yes
Main function of key system components	1) ECG measurement during using time 2) Check whether the device is working normally	1) ECG measurement during using time 2) Check whether the device is working normally	Yes
Wear period	Up to 14 days (ATP-C130) Up to 7 days (ATP-C70)	Up to 14 days (ATP-C130)	No
ECG channel	1 channel	1 channel	Yes
Recording Format	Continuous	Continuous	Yes
Input Impedance	> 10MΩ	> 10MΩ	Yes
RF Communication	2.4 GHz Bluetooth	2.4 GHz Bluetooth	Yes
Frequency of band	2400 ~ 2480 MHz	2400 ~ 2480 MHz	Yes
Power supply	DC 3V, Coin battery (CR2032)	DC 3V, Coin battery (CR2032)	Yes
Operational temperature	41 to 104 °F	41 to 104 °F	Yes
Operational humidity	10% to 95% (non-condensing)	10% to 95% (non-condensing)	Yes

App function	1. Check whether the device is working normally 2. Document symptom events	1. Check whether the device is working normally 2. Document symptom events	Yes

AT-Report of AT-Patch is substantially equivalent to the predicate device by GETEMED Medizin- und informationstechnik AG. The following comparison table is presented to demonstrate substantial equivalence

B. Comparison with predicate device (AT-Report)

Descriptive Information	Subject Device	Predicate Device 2	S.E.
Manufacturer	ATsens Co., Ltd	GETEMED Medizin-und informationstechnik AG	No
Device Name	AT-Report	CardioDay V2.5	No
510(k) number	K242583	K162023	No
Classification Product Code / Regulatory Number	DQK (21CFR§870.1425)	DQK (21CFR§870.1425)	Yes
Regulatory Class	2	2	Yes
Use environment	Hospital or clinic environment	Hospital or clinic environment	Yes
Indications for Use	The device is intended to measure, analyze, edit and report continuous electrocardiogram (ECG) information for long-term recording (ATP-C130: up to 14 days, ATP-C70: up to 7 days) by attaching to the patient's torso. ECG records are saved in the device during use and are not intended for real-time monitoring. After the wear period is completed, the ECG data is transmitted to the AT-Report. A primary analysis is performed by the algorithms within the AT-Report, and then a physician report is issued based on those results after a secondary analysis by a clinician or trained operator with experience in ECG analysis to correct any incorrectly detected events. The Physician report is offered to clinicians or physicians on an advisory basis only. The device is used by	The CardioDay V2.5 Holter Analysis Software is designed for the acquisition, analysis, edit, review, report, and storage of ambulatory and multi-parameter ECG data. Results of the automated analysis are intended to assist the physician in the interpretation of the recorded data. This information is not intended to serve as a substitute for the physician overread of the recorded ECG data. The CardioDay V 2.5 system is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric human patients. CardioDay V2.5 provides the user arrhythmia study and Holter analysis capabilities. Data acquired may be used for the following indications:	Yes

	patients as prescribed by physicians or medical personnel. It is indicated for use on patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, fatigue, or anxiety.	a. Evaluation of symptoms that may be caused by cardiac arrhythmia and/or conduction disturbances. b. Evaluation of symptoms that may be due to myocardial ischemia. c. Detection of ECG events that alter prognosis in certain forms of heart disease. d. Detection and analysis of pacemaker function and failure e. Determination of cardiac response to lifestyle f. Evaluation of therapeutic interventions g. Investigations in epidemiology and clinical trials	
Prescription or OTC	Prescription	Prescription	Yes
Other information			
Main purpose of ECG analysis software	ECG data view, analyze, edit, review, report and storage	ECG data view, analyze, edit, review, report and storage	Yes
LOC of software	Enhanced	Moderate	No
Target User	Trained ECG technician or clinician	Trained physician and ECG technician	Yes
The performance (Arrhythmia)	1. VE Isolated 2. VE Couplet 3. VE Run 4. VE Bigeminy 5. SVE Isolated 5. SVE Couplet 5. SVE Run 5. SVE Bigeminy 6. Sinus Bradycardia 7. Ventricular Tachycardia 8. Supraventricular Tachycardia 9. R-R Pause 10. N-N Delay 11. Atrial fibrillation	1. PVC 2. Couplet 3. Triplet (3beats) & VE run (4beats) 4. Bigeminy 5. SVE 6. Bradycardia 7. VE tachycardia 8. SVE tachycardia 9. R-R pause 10. N-N delay 11. AF 12. Vent. Escape	No
Algorithm	Rule-based algorithm	Rule-based algorithm	Yes

8.1 The same between Subject device and Predicate Device 1 (K203638)

1) Product Code

: The proposed product code of the subject device is DSH for Holter electrocardiograph. The subject

device belongs to the product code range of the predicate device in K203638.

2) Regulatory number and classification

: The proposed regulatory number of the subject device is 878.2800 and the classification is 2. It is the same regulatory number and classification as the predicate device in K203638.

3) Indications for Use

: The subject device is indicated for use to measure, analyze, and report electrocardiogram (ECG) information for long-term recording (ATP-C130: up to 14 days, ATP-C70: up to 7 days) by attaching to the skin surface. The predicate device is indicated for use to capture, save, and view symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. It is the same as K203638.

4) Prescription Use

: The subject device is a prescription use device. It is the same as K203638.

5) Use environment

: The subject device is a wearable device. Attachment of device and initial operation check are made at the hospital. After then, the patient can use this device while moving in daily life. It is the same as K203638.

6) Technical characteristic

: The technical characteristics of subject device and predicate device are the same. In the case of ATP-C130, there is a difference in appearance and size compared to the predicate device. ATP-C70 of the subject device differs in appearance, size, IP rating and maximum using time, the rest are the same.

7) Key system component

Subject device and predicate device are composed of device and App. It is the same as K203638.

8.2 Differences between Subject device and Predicate Device 1 (K203638)

1) Add Model name ATP-C70

: The subject device is compared with the predicate device, and the model name ATP-C70 has been added. The differences between ATP-C70 and ATP-C130 are as follows.

The placement of each device model is identical

Item	Subject device (ATP-C70)	Predicate device
Maximum Using time	Up to 7 days	Up to 14 days
IP rating	IP 44	IP 57

Appearance		
Size	1. Main Body: 32.6 × 39.6 × 7.7mm 2. Total: 74 × 47.1 × 8.4mm 3. Sub-Patch: 95 x 68.1 x 0.05 mm	1. Main body: 31 × 39 × 8.3mm 2. Total: 95 × 52.6 × 8.3mm 3. Patch: 95 x 52.6 x 0.5mm

※ ATP-C130 and ATP-C70 have the same circuit diagram, function, raw material, and manufacturing process except for the parts mentioned in the table above. Due to the IP rating, size, appearance and maximum using time mentioned above, there is no problem in achieving the purpose of use and function.
The difference in usage time between the models is because some users do not want to use it for a long time.

2) Change of ATP-C130
: Compared to the ATP-C130 model of the predicate device, the ATP-C130 of the subject device has some changes. The changes are as follows.

Item	ATP-C130 of subject device	ATP-C130 of predicate device
Appearance		

		
	The shape of the patch has changed compared to the previous device. In the predicate device, the patch and the device were integrated, but in the subject device, the patch was changed so that the patch could be attached as a Sub patch.	
Size	1. Main Body: 39 × 31 × 7.8mm 2. Total: 84 × 48.8 × 8.5mm 3. Sub-Patch: 104 x 68.8 x 0.05 mm	1. Main Body: 39 x 31 x 8.3mm 2. Patch: 95 × 52.6 × 8.3mm
	As the patch was divided into patch and sub-patch, the size was changed.	

Except for the above items, the predicate device and the subject device are the same.

8.3 The same between Subject device and Predicate Device 2 (K162023)

1) Product Code

: The proposed product code of the subject device is DQK for AT-Report. Predicate device also has the same DQK product code.

2) Regulatory number and classification

: The proposed regulatory number of the subject device is 870.1425, and the classification is 2. It is the same regulatory number and classification as the reference device in K162023.

3) Main purpose and function

: The AT-Report of the Subject device and CardioDay V2.5 of the Predicate device can view, analyze, edit, review, report and store the ECG data measured by the device to the software. Also results of automated ECG analysis are use to assist the physician in the interpretation of the recorded ECG data. There may be differences in the UI and interface, but the ECG analysis software incorporated in both the Subject device and the predicate device encompasses comparable primary functionalities. However, these differences do not significantly affect the purpose of using ECG analysis software.

4) Prescription Use

: The subject device is a prescription use device. It is the same as the predicate device (K162023).

5) Use environment

: The ECG analysis software of subject device and predicate device is used by hospital or clinic environment.

6) Intended User

: This product is intended for use by ECG professionals such as trained operators or clinicians. It is the same as the predicate device (K162023).

7) Algorithm

: The AT-Report software utilizes machine learning-based algorithms to automatically detect and classify arrhythmia events from ECG data recorded by the AT-Patch device.

8.4 Differences between Subject device and Predicate Device 2 (K162023)

1) UI and interface

: The ECG analysis software of predicate device and subject device has the same purpose of use, but there are differences in interface and UI. However, UI or interface has different parts for each manufacturer, and the validity of these has proven software validation through IEC 62304.

2) Level of Concern (LOC) of software

: The software LOC for the subject device is classified as 'enhanced', while the predicate device's software LOC is 'moderate'. This higher classification for the subject device is attributed to the potential for serious patient injury in the event of software malfunction. Although the analysis software functionalities of both devices are substantially similar, the severity of potential risk associated with software malfunction has been assessed differently.

The manufacturer has applied a more stringent evaluation of the risk associated with software malfunction for the subject device. It is important to note that this difference in software LOC classification does not impact the effectiveness or substantial equivalence of the two devices.

3) The performance (Arrhythmia)

Output Term (Arrhythmia term)		Remark
Subject Device	Predicate device (K162023)	
VE Isolated	PVC	Only terminology differs.
VE Couplet	Couplet	Only terminology differs.
VE Run	Triplet (3beats) & VE run (4beats)	Subject device groups 3+ beats as "VE Run", while Predicate device splits 3 and 4+ beats.
VE Bigeminy	Bigeminy	Only terminology differs.
SVE isolated	SVE	SVE includes SVE isolated, SVE couplet, SVE run, and SVE Bigeminy.
SVE couplet	SVE	
SVE run	SVE	
SVE Bigeminy	SVE	
Sinus bradycardia	Bradycardia	Only terminology differs.
Ventricular tachycardia	VE Tachycardia	Same
Supraventricular tachycardia	SVE Tachycardia	Same
R-R pause	R-R pause	Same
N-N delay	N-N delay	Same
Atrial fibrillation	AF	Same
-	Vent. Escape	Vent. Escape is implemented only in the Predicate device.

- Although the Subject Device and Predicate Device differ in output terminology and the types of arrhythmias included in each output, all outputs are identical except for the presence of Vent. Escape.
- The sole output difference, Vent. Escape, is not a mandatory performance requirement under international standards (ANSI EC57:2012 and IEC 60601-2-47:2012) and is an optional feature provided by specific manufacturers.
- Therefore, the presence or absence of Vent. Escape does not affect the Subject Device's ability

to achieve its intended purpose.

9. Performance Testing – Nonclinical

1) Electrical Testing and EMC Testing

The subject device is an electrical medical device. Electrical hazard, mechanical hazard and high temperature hazard are included within the device. The electrical and EMC tests were performed in accordance with the FDA recognized standards,

- IEC 60601-1:2005/2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-47:2012, Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic system.
- IEC 60601-1-2:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11:2015, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- RTCA-DO-16G:2010, Environmental conditions and test procedures for Airborne Equipment
- The test results meet with the electrical safety and EMC requirements.

2) Biocompatibility

The biocompatibility tests were performed in accordance with the FDA recognized standards,

- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ISO 10993-23:2021(E) Biological evaluation of medical devices – Part 23: Tests for irritation

3) Sterilization and Shelf-life test

This device is not sterile.

The shelf life of the device has been verified in accordance with internal criteria.

Testing conducted per internal protocols has confirmed that this device is suitable for use for up to 14 days and meets the 1-year warranty period requirements.

4) ECG Electrodes performance test

ECG Electrode was performed according to FDA Standard

- ANSI/AAMI EC12:2000 (R2015) Disposable ECG Electrodes

5) Cybersecurity test

Cybersecurity tests were performed in accordance the FDA recognized guidance.

- Cybersecurity in medical devices: quality system considerations and content of premarket submissions.
- FDA Act 524B

6) Software

Software validation was evaluated according to IEC62304:2015.

7) Energy Reduction

Energy reduction test was performed an alternative method refer to the test method of IEC 60601-1 Clause 8.5.5.2. The device was tested and demonstrated to be safe in case of defibrillation, however the device is not defibrillation-proof.

8) Coexistence test

Coexistence test was performed according to ANSI TIR 69:2017

9) Usability

Usability formative & summative test were performed according to IEC 62366-1:2015 and FDA guidance.

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10) Patch attachment position

The Patch attachment position test was performed according to the internal criteria.

11) Heart rate accuracy test

The heart rate accuracy test was performed according to the internal criteria

12) The performance (Arrhythmia) accuracy

The performance (Arrhythmia) accuracy test was evaluated in accordance with ANSI/AAMI EC57:2012, and the dataset used and the tests performed are summarized below.

Section	Content
Data Collection	ECG data was collected from diverse racial groups (White, Black, Hispanic, Asian), genders (male/female), ages (Young adulthood (18–39 years), Middle adulthood (40–64 years), Old age (Over 65 years)), and BMI categories (normal, overweight, obese), representing the U.S. population. The dataset was designed to closely align with U.S. demographics. Data was sourced from multiple hospitals and annotated by certified ECG technicians and cardiologists
Testing Performed	The collected dataset was used to evaluate the accuracy of QRS detection, VEB/SVEB detection, atrial fibrillation (AF) detection, Couplets, Runs, and Tachycardia detection. Performance was assessed based on Sensitivity, Positive Predictive Value (PPV), and False Positive Rate (FPR), validated against reference data.

11. Conclusion

The subject device and predicate device(K203638) have the same purpose, principle of operation, circuit diagram, and electrical characteristics in most parts. However, there are differences including maximum usage time, IP grade, appearance, size, and UI of the software depending on the model. However, the safety and performance test reports support the safety and effectiveness of the subject device as compared to the predicate.

In addition, the subject device and predicate device (K162023) have the same algorithm method, purpose of use, environment of use, and intended users. Although the type of arrhythmia detected is different from the software LOC, performance and safety tests ensure the substantial equivalence of the subject device.

In this regard, we conclude that the subject device is substantially equivalent to the predicate devices (K203638 & K162023).