October 12, 2022

ATsens Co., Ltd
% Do Kim
CEO
BT Solutions, Inc.
Unit 904, Eonju-ro 86-gil 5, Gangnam-gu
Seoul, Seoul 06210
Korea, South

Re: K203638
Trade/Device Name: AT-Patch
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: September 13, 2022
Received: October 7, 2022

Dear Do 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 (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)*
K203638

Device Name
AT-Patch

Indications for Use *(Describe)*
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 the device for review after the recording period (up to 14 days) is completed, and are not intended for for real-time monitoring. The device does not include automated ECG analysis functions, and the recorded ECGs are not intended for automated 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.

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

Preparation Date: October 7, 2022

1. Applicant / Submitter

Applicant/Submitter: ATsens Co.,Ltd/KeonHoon Lee
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2. Submission Contact Person

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3. Device Information

Trade Name	AT-Patch
Common Name	AT-Patch
Classification Name	Medical magnetic Tape Recorder
Classification Regulation	21CFR870.2800
Device Class	2
Product Code	DSH

4. Predicate Device

Manufacturer	iRhythm technologies, Inc.
Device Name	Zio SkyRunner(SR) ECG Monitoring service
510(k) number	K143513

5. Description

AT-Patch consists of 1) AT-Patch device, 2) Software for ECG viewing (ATR-C130), 3) App (ATN-C130) that communicates with the device and allows the patient to view the ECG waveform for visual assessment of the recording quality, and included parts (Dedicated Cable, BLE Dongle and USB memory).
AT-Patch an ambulatory ECG recorder, designed to continuously acquire and store patient's ECG for up to 14 days. The AT-Patch can connect to the device applicaitn (ATN-C130) torecord symptoms with the App during operation and to check the ECG recording. The device is not intended for real-time monitoring.

6. Technological Characteristic

ATP-C130		
	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	0.05Hz to 40Hz
Electrode	**AC impedance**	Less than 3KΩ (10Hz)
RF	**RF communication**	2.4GHz BLE 4.2
	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 8.1 or higher iOS 12.0 or higher
	Supported PC S/W Version	Window 10 (64bit)
Power Requirement	**Power Supply**	DC 3V, Coin Battery (CR2032)
	Intended use period	Up to 14 days

Physical Characteristics	**Total Size (L x W x H: mm)**	95 x 52.6 x 8.3
	Main Body Size (L x W x H: mm)	31 x 39 x 8.3
	Weight (g)	Main Body: Below 13g
	Lifetime	12 months
QoS	**Latency**	ATN-C130: less than 130msec ATR-C130: less than 150msec
	Throughput	ATN-C130: more than 12,000bps ATR-C130: more than 4,500bps
	Distance	Maximum 7 (m)

7. Intended Use / Indication for use

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 the device for review after the recording period (up to 14 days) is completed, and are not intended for for real-time monitoring. The device does not include automated ECG analysis functions, and the recorded ECGs are not intended for automated 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.

8. Device Components

1) AT-Patch Device (ATP-C130): The device that acquires and stores the patient's ECG signal for up to 14 days.
2) App (ATN-C130): App to check that the device is operating normally and allows the patient and caregiver to manually record symptoms. The app has the following features.
   2-1). Check if the device is operating normally (View ECG data – not intended for clinical or diagnostic uses)
   2-2). Symptom note recording (allows to manually note that a patient feels an abnormality while wearing it)
   2-3). Log-in function (user ID, password)
   2-4). Operation connection for start the device record 2-5). Software lock function
   - Live on view 60 minutes limit function per days
   - 30 minutes access limit in case of 5 consecutive login failures

- Login execution function when not in use for a long time (30 minutes)

3) AT-Report Software for ECG viewing (ATR-C130): Software that downloads the patient's ECG data saved in the device's memory and the symptom note record recorded by the patient from the App (ATN-C130) through a specific cable provided. The software also allows to visualize the ECG signal for manual interpretation. The software does not include automated ECG analysis. This software also provides the main functions of ATN-130 App via a BlueTooth dongle, allowing the use of the device by patients not having a mobile phone compatible with ATN-130 App.

Accessories:

- Cable
- BlueTooth Low Energy dongle

9. Substantial Equivalence Discussion

AT-Patch is substantially equivalent to the predicate device, Zio SR ECG Monitoring service (K143513). The following comparison table is presented to demonstrate substantial equivalence.

A. Comparison with predicate device

Descriptive Information	Subject Device	Predicate Device
Manufacturer	ATsens Co.,Ltd	iRhythm technologies, Inc.
Device Name	AT-Patch	Zio SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service
510(k) number	K203638	K143513
Classification Product Code / Regulatory Number	DSH (21CFR§870.2800)	DSH (21CFR§870.2800) DQK (21CFR§870.1425) DXH (21CFR§870.2920)
Regulatory Class	2	2
Patient environment	Ambulatory	Ambulatory
Patient population	Non-pediatric, Non-critical care patients	Non-pediatric, Non-critical care patients

Indications for Use	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 the device for review after the recording period (up to 14 days) is completed, and are not intended for for real-time monitoring. The device does not include automated ECG analysis functions, and the recorded ECGs are not intended for automated 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.	The ZIO SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult 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, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.
Prescription or OTC	Prescription	Prescription
Technological characteristics		
Key system components	1) AT-Patch 2) App 3) AT-Report	1) Zio SR Patch Recorder with Bluetooth technology 2) Zio SR Wireless Gateway 3) ZIO ECG Utilization Service System
Wear period	Up to 14 days	Up to 14 days
ECG channel	1 channel	1 channel

Recording Format	Continuous	Continuous
Input Impedance	≥ 10MΩ	≥ 10MΩ
RF Communication	2.4 GHz Bluetooth	2.4 GHz Bluetooth
Frequency of band	2400 ~ 2480 MHz	2400 ~ 2480 MHz
Power supply	DC 3V, Coin battery (CR2032)	DC 3V, Coin battery (CR2032) (2ea)
ECG analysis	View ECG	Rhythm types Beat Heart rates Runs
Operational temperature	41 to 104。F	41 to 104。F
Operational humidity	10% to 95% (non-condensing)	10% to 95% (non-condensing)
App function	1. Check whether the device is working normally 2. Document symptom events	1. Document symptom events
LOC of software	Major	Moderate

1. The same between Subject device and Predicate Device.

1) Product Code

The proposed product code of the subject device is DSH. This is the same product code of the predicate device in K143513.

2) Regulatory number and classification

The proposed regulatory number of the subject device is 878.2800 and the classification is 2. Compared to the predicate device, it does not contain 870.1425 and 870.2920. It is the same regulatory number and classification as the predicate device in K143513.

3) Indications for Use

The subject device is indicated for use to measure, save, and view electrocardiogram (ECG) information for long-term recording (up to 14 days) by attaching to the skin surface. The predicate device is indicated for use to capture, analyze, and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. It is similar as the predicate device in K143513.

4) Prescription Use

The subject device is a prescription use device. It is the same as the predicate devices in K143513.

5) Patients environment

The subject device is a wearable device. So, the patient can use this device while moving in daily life. It is the same as the predicate devices in K143513.

6) Technical characteristic

The key functions of the subject device are similar in most functions except in some components and App functions compared to the predicate device. The technological characteristics are similar compared to the predicate devices in K143513.

Performance test standard	Subject device	Predicate device
IEC 60601-1	o	o
IEC 60601-1-2	o	o
IEC 60601-1-6	o	o
IEC 60601-1-11	o	o
IEC 62304	o	o
IEC 62366	o	o
IEC 60601-2-47	o	o
ANSI/AAMI EC12	o	o
Cybersecurity test	o	o
Battery using time performance test	o	o
ISO 10993-1	o	o
ISO 10993-5	o	o
ISO 10993-10	o	o
ISO 10993-12	o	o
ISO 10993-23	o	-

1.2 Difference between Subject device and Predicate Device

1) Key system components

The subject device has different system components (AT-Patch, AT-Report and App). The subject device does not have wireless gateway. The wireless gateway of the predicate device role is a transmitter that sends a real-time recording such as ECG waveforms recorded in the app when the device is operated in iRhythm's monitoring

center for reporting. The subject device shows the electrocardiogram record in real time as an App solely for visual signal quality assessment, but does not have the function of sending it to a diagnostic center such as a hospital, therefore a wireless gateway is not needed for the subject device. ECG signals recorded by the subject device are not intended for automated analysis, and the subject device does not include automated analysis functions.

	Subject device	Predicate device
Same Component	1. AT-Patch 2. AT REPORT (ATR-C130) 3. App (ATN-C130)	1. Zio SR Patch recorder 2. Zio SR wireless Gateway 3. Zio ECG Utilization Service system
Different Component	-	Zio SR gateway

The presence or absence of a gateway does not affect the measurement, recording and analysis of data after use for 14 days, so subject device and predicate devices are not different due to this difference.

2) App function

: The subject device has a function to check whether the device is working normally through ECG waveform on the App compared to the predicated device. The subject device is a recorder, whereas the predicate device is a monitoring device. The predicate device can view the patient ECG waveform in the monitoring center for report of iRhythm technologies, Inc. The difference between the subject device and the predicate device is whether the corresponding function is implemented in the App or the monitoring center for reporting. The function of App allows the patient to check whether the device they are wearing is operating normally.

	Subject device	Predicate device
Same function	1. Document symptom events	1. Document symptom events
Different function	1. To check whether the device is working normally	-

※ The patient's waveform through the App is simply a means to check whether the device is working normally. The record is not saved. It is impossible to analyze any symptoms such as arrhythmia through this. Therefore, whether the waveform is viewed by the patient or at the center, it is a difference in convenience and not in function that has any influence on the purpose of use of the product. Therefore, the difference in App function does not affect the equivalence with the predicate device.

3) Indication for use

: The subject device is indicated for use to measure, save, and view electrocardiogram (ECG) information for long-term recording (up to 14 days) by attaching to the skin

surface. The predicate device is indicated for use to capture, analyze, and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring.

	Subject device	Predicate device
Same part	continuously measure, save and view patient's ECG	continuously measure, save and view patient's ECG
Different part	View ECG information for long- term recording (up to 14 days) by attaching to the skin surface.	analyze, and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring

4) ECG Analysis software

The subject device does not have ECG analysis functions. By receiving the patient's data stored in the device, you can manage information including the patient's ECG data and view the patient's ECG. On the other hand, the predicate device can analyze, and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information in their ECG Analysis Software.

	Subject device	Predicate device
Same function	1. Patient information management 2. View patients ECG data	1. Patient information management 2. View patients ECG data
Different function	-	Analyze, and report patients ECG data

The subject device has been tested about electrical safety, EMC, biocompatibility, and performance. The results show that these differences do not raise any problems in the safety and effectiveness

10. 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

The test results met the electrical safety and EMC requirements.

11. Performance Testing - Nonclinical

1) 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

2) Sterilization and Shelf life test

This device is not sterile.
The shelf life of device was verified in accordance with the internal criteria.

As a result of testing according to the internal criteria, it has been verified that this device can be use for up 14 days and satisfies the warranty period of 1 year.

3) ATP-C130 intended using time test

As a result of testing according to the internal criteria, it has been verified that this device can be used for up 14 days.

4) Patch adhesion persistence test

Patch adhesion persistence test was performed in accordance with FDA Standard

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

5) ECG Electrodes performance test

ECG Electrode was performed according to FDA Standard

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

6) Cybersecurity test

Cybersecurity tests were performed in accordance the FDA recognized guidance.

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices issued in 2018.

7) Extractable Substance Test

The extractable substance tests were performed about PH, Potassium permanganate-reducible substances, Residue on evaporation, UV spectrum and Heavy metals.

8) ECG Electrodes test

ECG Electrodes tests were performed in accordance 'ANSI/AAMI EC12:2000(R2015)'.

9) Software

Software validation was evaluated according to IEC62304:2015.

10) Energy reduction

Energy reduction tests were performed using alternative method of IEC 60601-1 Clause 8.5.5.2. The device was demonstrated to be safe in case of defibrillation, however the device is not defibrillation-proof.

11) QoS

Qos test are performed according to ANSI TIR 69:2017

12) Usability

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

The Test results met the performance requirements.

12. Conclusion

In comparison between the subject device and the predicate device, there are the similar indications for use, principle of operation, and technological characteristics. Although there are some differences (e.g., App function, system components, medical process and ECG Analysis function), they do not raise new or different questions of safety and effectiveness as compared to the predicate device. Results of the tests performed support the claims of substantial equivalence.

In this regard, we conclude that the subject device is substantially equivalent to the predicate device.