July 8, 2024

RhythMedix LLC
Stan Biletsky
Cto
5000 Atrium Way
Ste 1
Mount Laurel, New Jersey 08054

Re: K233584
Trade/Device Name: RhythmStar System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: QYX
Dated: June 7, 2024
Received: June 7, 2024

Dear Stan Biletsky:

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.

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 Shih Kozen
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics and Monitoring Devices
OHT2: Office of Cardiovascular Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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.

Submission Number *(if known)*

K233584

Device Name

RhythmStar System

Indications for Use *(Describe)*

The RhythmStar system is intended for use by patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis. The device continuously records ECG and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers all recorded cardiac activity to the cloud server where it is presented and can be retrospectively reviewed by a medical professional at a monitoring center. The RhythmStar system is not intended for real-time monitoring.

The data received from the RhythmStar device can be used for retrospective review, arrhythmia analysis, and further evaluation, reporting and signal measurements using RhythmStar system or a compatible arrhythmia analysis software that has been FDA cleared for Lead II analysis using non-traditional wet electrode placement. The RhythmStar system is not intended to sound any alarms.

The device does not deliver any therapy, administer any drugs, or provide for life support. The RhythmStar system does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibility of a physician. RhythmStar is for prescription use only.

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.

Summary of 510(k)

RhythMedix, LLC

This 510(k) Summary is in conformance with 21 CFR 807.92

Submitter: RhythMedix, LLC
5000 Atrium Way Ste. 1
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United States

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Company Contact: Stan Biletsky, CTO
RhythMedix, LLC
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Device Name and Classification

Trade Name: RhythmStar System
Common Name: Outpatient cardiac telemetry
Classification: Class II
Regulation Number: 21 CFR 870.1025
Classification Panel: Cardiovascular
Product Code: QYX

Predicate Device:

Primary Predicate	
Trade Name	RhythmStar System
Common Name	Telephone electrocardiograph transmitter and receiver
510(k) Submitter / Holder	RhythMedix, LLC
510(k) Number	K141813
Regulation Number	21 CFR Part 870.2920
Classification Panel	Cardiovascular
Product Code	DXH
Secondary Predicate	
Trade Name	Zio AT ECG Monitoring System
Common Name	Outpatient cardiac telemetry
510(k) Submitter / Holder	iRhythm Technologies, Inc.
510(k) Number	K163512
Regulation Number	21 CFR Part 870.1025
Classification Panel	Cardiovascular
Product Code	QYX, DQK, DSH, DSI, DXH

Device Description

The RhythmStar system consists of the RhythmStar device and the server. The RhythmStar device is a portable, battery-powered, wireless cardiac monitor which may be worn by a patient to record ECG and activity level data for up to 30 consecutive days. The device can capture patient activated and auto-triggered events such as Bradycardia, Tachycardia, and Atrial Fibrillation as identified by an embedded arrhythmia detection algorithm. The device is capable of automatically delivering the collected ECG data to the server using a built-in 4G LTE wireless data modem, or the data can be transferred from the device using a USB connection. The data transmitted by the RhythmStar device can be stored, evaluated, and presented for review, analysis and reporting by a medical professional using a server, such as the RhythmStar System server.

Indications for Use

The RhythmStar system is intended for use by patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis. The device continuously records ECG and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers all recorded cardiac activity to the cloud server where it is presented and can be retrospectively reviewed by a medical professional at a monitoring center. The RhythmStar system is not intended for real-time monitoring.

The data received from the RhythmStar device can be used for retrospective review, arrhythmia analysis, and further evaluation, reporting and signal measurements using RhythmStar system, or a compatible arrhythmia analysis software that has been FDA cleared for Lead II analysis using non-traditional wet electrode placement. The RhythmStar system is not intended to sound any alarms.

The device does not deliver any therapy, administer any drugs, or provide for life support. The RhythmStar system does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibility of a physician. RhythmStar is for prescription use only.

Risk Analysis Method

The updated RhythmStar monitoring device was assessed to determine the risks of the device as it relates to the hardware changes. A risk analysis was conducted in accordance with ISO 14971:2019, Medical devices – Application of risk management to medical devices.

Substantial Equivalence Discussion

The table below provides a side-by-side comparison between RhythmStar RS-10003 and the predicate devices with respect to the intended use, technological characteristics, and principles of operation.

Table 1. Substantial Equivalence Table

Characteristic	Subject Device RhythmStar RS-10003	Primary Predicate Device RhythmStar RS-10002 (K141813)	Secondary Predicate Device Zio® QX ECG Monitoring System (K163512)	Comparison
Intended Use				
Intended Use	The RhythmStar System is intended for continuous ECG monitoring and arrhythmia detection.	The RhythmStar System is intended for continuous ECG monitoring and arrhythmia detection.	The Zio® QX ECG Monitoring System is intended for continuous ECG monitoring and arrhythmia detection.	Identical
Indications for Use				
Indications for Use	The RhythmStar RS-10003 System is intended for use by patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis. The device continuously records ECG data and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers all recorded cardiac activity to the cloud server where it is presented and can be reviewed by a	The RhythmStar System is intended for use by patients who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis. The device continuously records ECG data and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers the recorded cardiac activity to the server where it is presented and	The Zio QX ECG Monitoring System is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram (ECG) information for long-term monitoring. While continuously recording patient ECG, both patient-triggered and automatically detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, a final report is generated based on beat-to-beat information from the entire ECG recording. It is indicated for	Equivalent

Characteristic	Subject Device RhythmStar RS-10003	Primary Predicate Device RhythmStar RS-10002 (K141813)	Secondary Predicate Device Zio® QX ECG Monitoring System (K163512)	Comparison
	medical professional at a monitoring center. The RhythmStar system is not intended for real-time monitoring. The data received from the RhythmStar device can be used for retrospective review, arrhythmia analysis, reporting and signal measurements by RhythmStar system, or a compatible arrhythmia analysis software that has been FDA cleared for Lead II analysis using non-traditional wet electrode placement. The RhythmStar is not intended to sound any alarms. The device does not deliver any therapy, administer any drugs, or provide for life support. The RhythmStar system does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibility of a physician. RhythmStar is for prescription use only.	can be reviewed by a medical professional. The data received from the RhythmStar device can be used by another device for arrhythmia analysis, reporting and signal measurements. The RhythmStar is not intended to sound any alarms. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements, or provide for any life support. RhythmStar is for prescription use only.	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, pre-syncope, syncope, fatigue, or anxiety. The reports are provided for review by the intended user to render a diagnosis based on clinical judgment and experience. It is not intended for use on critical care patients.	

Characteristic	Subject Device RhythmStar RS-10003	Primary Predicate Device RhythmStar RS-10002 (K141813)	Secondary Predicate Device Zio® QX ECG Monitoring System (K163512)	Comparison
Device Use				
Prescription / OTC	Prescription	Prescription	Prescription	Identical
Intended Population	Patients requiring cardiac monitoring who are ambulatory and without life-threatening conditions	Patients requiring cardiac monitoring who are ambulatory and without life-threatening conditions	Patients requiring cardiac monitoring who are ambulatory and without life-threatening conditions	Identical
Environment of Use	Ambulatory, Outpatient	Ambulatory, Outpatient	Ambulatory, Outpatient	Identical
Technological Characteristics				
Dimensions	59mm x 50mm x 15mm	101mm x 66mm x 13mm	Patch 5.2 x 2.0 x 0.5 in (132mm x 51mm x 13mm) Gateway 6.2 x 3.4 x 0.8 in (157mm x 86mm x 20mm)	Different – This difference does not change the intended use of the device. Both devices are wearable and portable. The safety and effectiveness of the size has been demonstrated through testing.
Weight	38 g	90 g	24.7 g	Different – This difference does not change the intended use of the device. The safety and effectiveness of the size has been demonstrated through testing.
Material	ABS and TPU plastic	ABS and TPU plastic	Proprietary patch and plastic	Identical to primary predicate
Duration of Use	Up to 30 days	Up to 30 days	Up to 14 days	Identical to primary predicate
Type of Wear	Device worn on chest	Device worn over belt / waistband	Device worn on chest	Identical to secondary predicate

Characteristic	Subject Device RhythmStar RS-10003	Primary Predicate Device RhythmStar RS-10002 (K141813)	Secondary Predicate Device Zio® QX ECG Monitoring System (K163512)	Comparison
Basic Technology	Analog ECG front-end, accelerometer, MCU, flash data storage, built-in cellular modem for data transmission	Analog ECG front-end, accelerometer, MCU, flash data storage, built-in cellular modem for data transmission	Analog ECG recorded on patch and transmitted via Bluetooth to Gateway with built-in cellular modem for data transmission	Identical to primary predicate
Battery Powered	Yes	Yes	Yes	Identical
Energy Source	Rechargeable 3.7V Li-ion battery	Rechargeable 3.7V Li-ion battery	Patch Lithium Manganese Dioxide Coin Cells Gateway 1 Lithium Polymer Cell	Identical to primary predicate
Battery Life	72 hours	72 hours	14 days	Identical to primary predicate
Removable Battery	No	Yes	No	Identical to secondary predicate
Bandwidth	0.05 … 40 Hz	0.05 … 40 Hz	0.5 … 30 Hz	Identical to primary predicate
Common-mode rejection ratio (CMRR)	100 dB minimum, 115 dB typical	90 dB minimum, 100 dB typical	Information not available	Different – The subject device has a higher CMRR to improve common mode rejection. This difference does not change the intended use of the device. The safety and effectiveness of the CMRR difference has been demonstrated via IEC 60601-2-47.

Characteristic	Subject Device RhythmStar RS-10003	Primary Predicate Device RhythmStar RS-10002 (K141813)	Secondary Predicate Device Zio® QX ECG Monitoring System (K163512)	Comparison
Sampling Rate	256 Hz	250 Hz	200 Hz	Different – This change does not change the intended use of the device. Both devices support a 125 Hz sampling rate, which is the minimum sample rate needed to support the bandwidth requirement cited in IEC 60601-2-47 for ambulatory arrhythmia monitoring.
ECG leads	2	2, 3, 4, 5	2	Identical to secondary predicate device.
ECG Acquisition	Body worn monitoring device	Body worn monitoring device	Body worn monitoring device	Identical
Lead off Detection	Yes	Yes	Patch off detection	Identical to primary predicate device
Accelerometer	Yes	Yes	Information not available	Identical to primary predicate
Display	LED lights	LCD	LED lights	Identical to secondary predicate
User Event Trigger	Double tap on monitoring device	Button push on monitoring device	Button push on patch	Different – This difference does not change the intended use of the device. The subject device and predicate devices provide a method of manual event triggering.
Wireless Communication Technology	Yes - 4G mobile network using embedded cellular data modem	Yes - 3G mobile network using embedded cellular data modem	Yes	Equivalent - Both devices use cellular communication technology and operate on the same mobile networks.
System Design	PEMS and software	PEMS and software	PEMS and software	Identical

Characteristic	Subject Device RhythmStar RS-10003	Primary Predicate Device RhythmStar RS-10002 (K141813)	Secondary Predicate Device Zio® QX ECG Monitoring System (K163512)	Comparison
Sterile	Non-sterile	Non-sterile	Non-sterile	Identical
Use Type	Multi-Patient Use	Multi-Patient Use	Single Use Only	Identical to primary predicate device
Arrhythmia Detection Algorithm	Yes	Yes	Yes	Identical
Alarms	None	None	None	Identical
Adjustable Device Programming Parameters	Yes	Yes	No	Identical to primary predicate device
Review of ECG Data	ECG Technicians at 24/7 Monitoring Center	ECG Technicians at 24/7 Monitoring Center	ECG Technicians at 24/7 Monitoring Center	Identical

In conclusion, the intended use for RhythmStar RS-10003 is identical to the intended use of the primary predicate (RhythmStar System (K141813)) and secondary predicate (Zio® QX ECG Monitoring System (K163512)) with regard to continuous ECG monitoring and arrhythmia detection. Additionally, the technological characteristics are equivalent to those of the primary predicate (RhythmStar System (K141813)) and the secondary predicate (Zio® QX ECG Monitoring System). Testing demonstrates that RhythmStar RS-10003 is substantially equivalent to the predicate devices (RhythmStar System (K141813) and Zio® QX ECH Monitoring System (K163512)) and is as safe and effective as the predicate devices.

Testing

Biocompatibility

Biocompatibility of the RhythmStar device was evaluated in accordance with ISO 10993 (see K141813).

Electrical Safety and EMC Testing

The RhythmStar RS-10003 was tested and conforms to the following FDA recognized consensus standards:

1. IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
3. IEC 60601-1-6: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
4. IEC 60601-1-11: Medical electrical equipment – Part 1-11: 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
5. ANSI/AAMI/IEC 60601-2-47: Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
6. AIM 7351731: Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
7. IEEE ANSI USEMCSC C63.27 American National Standard for Evaluation of Wireless Coexistence.

The RhythmStar RS-10003 was also evaluated in accordance with the following FDA guidance documents.

1. Electromagnetic Compatibility (EMC) of Medical Devices, *Guidance for Industry and Food and Drug Administration Staff*
2. Radio Frequency Wireless Technology in Medical Devices, *Guidance for Industry and Staff*

The RhythmStar RS-10003 is not defibrillation proof but was tested to demonstrate safety in case of defibrillation.

Software Verification and Validation

The RhythmStar RS-10003 software was developed and is maintained in accordance with IEC 62304 Medical device software – Software life cycle processes.

Software used in the RhythmStar RS-10003 went through unit testing, integration testing, and system-level testing.

Performance Testing

The RhythmStar System was tested in accordance with ANSI/AAMI EC57 (see K141813).

Bench testing also confirmed that the RhythmStar RS-10003 can continuously record ECG signal, store ECG data, and transmit manual or auto-activated event recordings to the server via mobile network or USB connection for evaluation by a medical professional.

The RhythmStar RS-10003 monitoring device was tested in accordance with ANSI/AAMI EC53: ECG trunk cables and patient leadwires.

The RhythmStar RS-10003 monitoring device was tested in accordance with ANSI/AAMI EC12: Disposable ECG electrodes.

Cybersecurity Testing

Cybersecurity activities were performed in accordance with Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.

Conclusion

The intended use of the RhythmStar RS-10003 is identical to the intended use of the predicate device (K141813). Additionally, the technological characteristics of the subject device and predicate device (K141813) are equivalent and any differences do not raise new questions of safety and effectiveness. Based on device performance test results, RhythMedix determines that the RhythmStar RS-10003 performs within its design specifications, and is substantially equivalent to the predicate device.