April 21, 2026

RhythMedix LLC
% Rita King
Chief Executive Officer
MethodSense, Inc.
1 Copley Parkway
Suite 130
Morrisville, North Carolina 27560

Re: K250793
Trade/Device Name: RhythmStar System (SL)
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: March 27, 2026
Received: March 27, 2026

Dear Rita King:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K250793

Device Name
RhythmStar System

Indications for Use *(Describe)*
The RhythmStar SL 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 medical professional at a monitoring center. The RhythmStar SL is not intended for real-time monitoring.

The data received from the RhythmStar SL can be used for retrospective review, arrhythmia analysis, and further evaluation, reporting and signal measurements using RhythmStar system. The RhythmStar SL is not intended to sound any alarms.

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

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

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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

Primary Contact: Rita King, CEO
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Company Contact: Stan Biletsky, CTO
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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	Outpatient Cardiac Telemetry
510(k) Submitter / Holder	RhythMedix, LLC
510(k) Number	K233584
Regulation Number	21 CFR Part 870.1025
Classification Panel	Cardiovascular
Product Code	QYX

The predicate device has not been subject to a design-related recall.

Device Description

The RhythmStar system (model: **SL**) 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 SL 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 SL is not intended for real-time monitoring.

The data received from the RhythmStar SL can be used for retrospective review, arrhythmia analysis, and further evaluation, reporting and signal measurements using RhythmStar system. The RhythmStar SL is not intended to sound any alarms.

The device does not deliver any therapy, administer any drugs, or provide for life support. The RhythmStar SL does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibility of a physician. RhythmStar SL 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 a hardware modification. A risk analysis was conducted in accordance with ISO 14971:2019, Medical devices – Application of risk management to medical devices. No new risks or changes to existing risks were identified.

Substantial Equivalence

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

Table 1. Substantial Equivalence Table

Characteristic	Subject Device RhythmStar SL	Primary Predicate Device RhythmStar RS-10003 (K233584)	Comparison
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.	Identical
Indications for Use	The RhythmStar SL 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 medical professional at a monitoring center. The RhythmStar SL is not intended for real-time monitoring. The data received from the RhythmStar SL can be used for retrospective review, arrhythmia analysis, and further evaluation, reporting and signal measurements using RhythmStar system. The RhythmStar SL is not intended to sound any alarms. The device does not deliver any therapy, administer any drugs, or provide for life support. The RhythmStar SL does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibility of a physician. RhythmStar SL is for prescription use only.	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 all recorded cardiac activity to the cloud server where it is presented and can be 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.	Equivalent

Characteristic	Subject Device RhythmStar SL	Primary Predicate Device RhythmStar RS-10003 (K233584)	Comparison
Prescription / OTC	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	Identical
Environment of Use	Ambulatory, Outpatient	Ambulatory, Outpatient	Identical
Dimensions	59mm x 50mm x 15mm	59mm x 50mm x 15mm	Identical
Weight	38 g	38 g	Identical
Material	ABS and TPU plastic	ABS and TPU plastic	Identical
Duration of Use	Up to 30 days	Up to 30 days	Identical
Type of Wear	Device worn on chest	Device worn on chest	Identical
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	Identical
Battery Powered	Yes	Yes	Identical
Energy Source	Rechargeable 3.7V Li-ion battery	Rechargeable 3.7V Li-ion battery	Identical
Battery Life	72 hours	72 hours	Identical
Removable Battery	No	No	Identical
Bandwidth	0.05 … 40 Hz	0.05 … 40 Hz	Identical
Common-mode rejection ratio (CMRR)	100 dB minimum, 115 dB typical	100 dB minimum, 115 dB typical	Identical
Sampling Rate	256 Hz	256 Hz	Identical
ECG leads	2	2	Identical
ECG Acquisition	Body worn monitoring device	Body worn monitoring device	Identical
Distance between the electrodes	5.5”	7.5’’	Different – This change does not affect the intended use of the device. Substantial Equivalence of the device have been demonstrated through performance testing.
Lead off Detection	Yes	Yes	Identical
Accelerometer	Yes	Yes	Identical
Display	LED lights	LED lights	Identical
User Event Trigger	Double tap on monitoring device	Double tap on monitoring device	Identical

Characteristic	Subject Device RhythmStar SL	Primary Predicate Device RhythmStar RS-10003 (K233584)	Comparison
Wireless Communication Technology	Yes - 4G mobile network using embedded cellular data modem	Yes - 4G mobile network using embedded cellular data modem	Identical
System Design	PEMS and software	PEMS and software	Identical
Sterile	Non-sterile	Non-sterile	Identical
Use Type	Multi-Patient Use	Multi-Patient Use	Identical
Arrhythmia Detection Algorithm	Yes	Yes	Identical
Alarms	None	None	Identical
Adjustable Device Programming Parameters	Yes	Yes	Identical
Review of ECG Data	ECG Technicians at 24/7 Monitoring Center	ECG Technicians at 24/7 Monitoring Center	Identical
Ingress Protection (IP) rating	IP26 (product is protected from touch by fingers and objects larger than 12.5 millimeters, and it's also protected against powerful water jets from any direction)	IP26 (product is protected from touch by fingers and objects larger than 12.5 millimeters, and it's also protected against powerful water jets from any direction)	Identical

Testing

The RhythmStar SL performed the following evaluations in K233584. The change to the subject device from the predicate device included shortening the leadwire and revising the placement of the ECG electrodes. Information was provided to support the applicability of prior evaluations for the following:

Electrical Safety and EMC Testing

Electrical safety of the RhythmStar device was performed in accordance with the applicable standards and guidance documents in K233584.

Software Verification and Validation

The RhythmStar software was developed and is maintained in accordance with IEC 62304 Medical device software – Software life cycle processes. All relevant processes including the software development process, risk management activities, verification & validation, configuration management, maintenance, and problem resolution procedures have been implemented and maintained in accordance with IEC 62304 requirements (see K233584).

Performance Testing

The RhythmStar System was tested in accordance with ANSI/AAMI EC57 (see K233584).

Performance testing confirmed the RhythmStar device met the requirements of ANSI/AAMI EC53 and ANSI/AAMI EC12 in K233584.

The following evaluations were performed for the RhythmStar SL in support of this submission:

Biocompatibility

Biocompatibility of the RhythmStar device was evaluated in accordance with ISO 10993-1.

Performance Testing

Additional performance testing was conducted as part of this submission to demonstrate that the hardware modification and adjusted device placement do not affect performance of the unchanged arrhythmia detection algorithm. This performance testing included evaluating algorithm performance using the new lead placement on a dataset derived from patients in real-world clinical settings as well as demonstrating identical beat detection compared to the predicate using a side-by-side comparison with patients wearing the subject device and predicate simultaneously.

Cybersecurity Testing

Cybersecurity penetration and vulnerability testing was performed to identify vulnerabilities and exploits in accordance with FDA Guidance, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*.

Conclusion

In conclusion, the intended use for RhythmStar SL is identical to the intended use of the primary predicate (RhythmStar System (K233584)) with regard to continuous ECG monitoring and arrhythmia detection. Additionally, the technological characteristics of the subject device are equivalent to those of the predicate (RhythmStar System (K233584)). Testing demonstrates that the RhythmStar SL is substantially equivalent to the predicate device (RhythmStar System (K233584)).