July 11, 2025

VivaQuant, Inc.
% Kathy Herzog
Sr. Regulatory, Quality, and Compliance Consultant
DuVal & Associates, P.A.
1820 Medical Arts Building
825 Nicollet Mall
Minneapolis, Minnesota 55402

Re: K241179
Trade/Device Name: Rhythm Express Remote Cardiac Monitoring System (RX-1 mini)
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: QYX, MLO, DSI
Dated: July 11, 2025
Received: July 10, 2025

Dear Kathy Herzog:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241179

Device Name
Rhythm Express Remote Cardiac Monitoring System (RX-1 mini)

Indications for Use *(Describe)*
The Rhythm Express remote cardiac monitoring system is intended for use by patients greater than 10 kg 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 for review by a medical professional. The data received from the Rhythm Express device can be used by another compatible device for arrhythmia analysis, reporting and signal measurements. The Rhythm Express device is not intended to be used as part of an alarm system or for active patient monitoring.

The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support. The Rhythm Express system communicates events from the patient to the monitoring center within one to seven minutes (assuming cell service is available) and hence is not suitable for use as a real-time arrhythmia event monitor.

This device is not intended for patients in whom quantification of triplets/couplets is needed.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

K241179
510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

I. SUBMITTER

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Arden Hills, MN 55112

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bbrockway@vivaquant.com

Regulatory Contact: Kathy Herzog, DuVal & Associates, P.A.
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herzog@duvalfdalaw.com

Date Prepared: June 25, 2025

II. DEVICE

Name of Device:	RX-1 *mini* Rhythm Express Remote Cardiac Monitoring System
Classification Name:	870.1025 Arrhythmia Detector and Alarm 870.2800 Medical Magnetic Tape Recorder;
Common or Usual Name:	Ambulatory Cardiac Monitor
Device Panel:	Cardiovascular
Regulatory Class:	Class 2
Product Code:	QYX, MLO, DSI

III. PREDICATE DEVICE

RX-1 Rhythm Express Remote Cardiac Monitoring System, K200833.

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

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The RX-1 *mini* Rhythm Express Remote Cardiac Monitoring System (RCMS) is a multiple function device consisting of three components: 1) the RX-1 *mini* remote cardiac monitoring device ("RX-1 *mini* device") with on-board ECG waveform analysis algorithm, 2) the Web Service (RS-1) with server and database, and 3) back-office software (Operator Portal and Clinic Portal). The RS-1 server, Operator Portal, and Clinic Portal are non-device software functions.

The RX-1 *mini* device is worn by patients for a period of time as prescribed by a physician, up to 30 days, and continuously monitors ECG. The RX-1 *mini* device functions in one of three modes: a) Outpatient Cardiac Telemetry (OCT), b) Event Recorder (ER), and c) Wireless Holter monitor (WH). The device connects to standard ECG electrodes to capture 2 channel ECGs. The embedded algorithm processes the acquired ECG to detect arrhythmias, compress the ECG, and remove most in-band noise without distorting ECG morphology. The RX-1 *mini* device incorporates a cellular modem and Wi-Fi to communicate with the RS-1 Web Service.

The RX-1 *mini* device is not a life-supporting or life-sustaining system. Clinical judgment and experience are used to check and interpret the data. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements.

V. INDICATIONS FOR USE

The Rhythm Express remote cardiac monitoring system is intended for use by patients greater than 10 kg 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 for review by a medical professional. The data received from the Rhythm Express device can be used by another compatible device for arrhythmia analysis, reporting and signal measurements. The Rhythm Express device is not intended to be used as part of an alarm system or for active patient monitoring.

The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support. The Rhythm Express system communicates events from the patient to the monitoring center within one to seven minutes (assuming cell service is available) and hence is not suitable for use as a real-time arrhythmia event monitor.

This device is not intended for patients in whom quantification of triplets/couplets is needed.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The RX-1 *mini* Rhythm Express RCMS has the same intended use and indications for use as the predicate RX-1 Rhythm Express RCMS. The RX-1 *mini* device has the same following technological characteristics as the RX-1 device:

- Cardiac monitoring modes;
- Ingress protection;
- Housing material and housing label material;
- ECG algorithm design;
- ECG performance standard;
- ECG input (2 channels, 4 leads);
- Heart rate range;
- Device set up;

- Electrical parameters ;
- Event storage;
- Battery type, fuel gauge, charge chip;
- Recharge cycles;
- Venting;
- Ability for over-the-air updates;
- Data storage/report delivery to users;
- Physician access to full disclosure data;
- System component types;
- Environmental parameters; and
- Reuse.

Differences in technological characteristics of the RX-1 *mini* device as compared to the predicate RX-1 device include:

- Smaller housing size and lighter device weight;
- New patient contacting material (lead material);
- Simplified user interface (with LED and haptic feedback);
- Additional events detected (the subject device detects the same events as the predicate device with added ability to detect SVEs, VT, and SVT);
- Change in ECG lead length (shorter vector length);
- Smaller battery and change to magnetic charger port; and
- Addition of Wi-Fi and Bluetooth electronic interfaces.

VII. PERFORMANCE DATA

The following tests were completed to verify the safety and performance of the RX-1 *mini* Rhythm Express RCMS:

1) EMC testing
2) Electrical safety
3) External defibrillation safety (energy reduction testing)
4) Wireless Functionality and Coexistence
5) Mechanical and Environmental
6) Electrode adhesion for up to 3 days use with Ambu BlueSensor VLC electrodes
7) Biocompatibility
8) Usability
9) Performance testing to IEC 60601-2-47
10) ECG Signal Quality Clinical Equivalence
11) ECG algorithm performance
12) Software functionality
13) Cybersecurity

Testing was completed to the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] - Medical electrical equipment - Part

1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
- IEC 60601-1-6: 2010, AMD1:2013 – Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021] – 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 (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)]
- IEC 60601-2-47:2012/(R)2016 – Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- IEC 61000-4-2:2008 – Testing and measurement techniques - Electrostatic discharge immunity test
- ANSI AAMI IEC 62304:2006/A1:2016 – Medical Device Software – Software life cycle processes [Including Amendment 1 (2016)]
- ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text) – Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1
- IEEE ANSI C63.27-2017 – American National Standard for Evaluation of Wireless Coexistence
- IEEE C95.1-2005 – Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz
- AAMI TIR 36:2007 – Validation of software for regulated processes
- AAMI TIR57:2016 – Principles for medical device security - Risk management
- AAMI TIR97:2019 – Principles for medical device security - Postmarket risk management for device manufacturers
- ANSI AAMI EC53:2013/(R)2020 – ECG trunk cables and patient leadwires
- IEC 60529 Ed 2.2 b:2013 – Degrees of Protection Provided by Enclosures (IP Code)
- ANSI AAMI ISO 10993-1: 2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ANSI AAMI ISO 10993-5:2009/(R)2014 – Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Fourth edition 2021-11 – Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-12 Fifth edition 2021-01 – Biological evaluation of medical devices Part 12: Sample preparation and reference materials
- ISO 10993-23 First edition 2021-01 – Biological evaluation of medical devices Part 23: Tests for irritation

- UN DOT 38.3 2016 – Testing for Lithium-Ion Batteries
- IEC 62133-2 Edition1.0 2017-02 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them for use in portable applications – Part 2: Lithium systems
- AINSI AAMI ISO 14971:2019 – Medical devices - Applications of risk management to medical devices
- ISO 15223-1 Fourth edition 2021-07 – Medical devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
- IEC TS 60601-4-2 Edition 1.0 2024-03 – Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 61000-4-3:2020 – Electromagnetic compatibility (EMC) Testing and measurement techniques – Radiated, radio-frequency electromagnetic field immunity test.
- CVSS 3.1 – Common Vulnerability Scoring System v3.1: Specification Document
- ANSI AAIMI EC57:2012 – Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
- ANSI AAMI EC12:2000/(R)2015 – Disposable ECG electrodes

Performance testing verifies that the RX-1 *mini* Rhythm Express RCMS meets performance specifications.

VIII. CONCLUSIONS

The subject RX-1 *mini* Rhythm Express RCMS has the same intended use and indications for use as the predicate RX-1 Rhythm Express RCMS. The differences in technological characteristics of the RX-1 *mini* device as compared to the RX-1 device do not raise different questions of safety or effectiveness. Performance testing data demonstrate that the subject device is as safe, and as effective, as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device (K200833).