September 2, 2020

VivaQuant Inc.
% Brodie Pedersen
Consultant
Borderless Compliance, LLC
7118 Teakwood Cir
Maple Grove, Minnesota 55369

Re: K200833
Trade/Device Name: RX-1 Rhythm Express Remote Cardiac Monitoring System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MLO, DSI
Dated: July 31, 2020
Received: August 3, 2020

Dear Brodie Pedersen:

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,

for

Jennifer Shih
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200883

Device Name
RX-1 Rhythm Express Remote Cardiac Monitoring System

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 device for arrhythmia analysis, reporting and signal measurements. The Rhythm Express device 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. 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.

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

(as required by 21CFR 807.92)

I. SUBMITTER

VivaQuant Inc.
4339 Nancy Place, Suite 100,
St. Paul, MN 55126
Contact Person: Brian Brockway
bbrockway@vivaquant.com
Phone: 651-217-2176
Date Prepared: July 31, 2020

II. DEVICE

Name of Device: RX-1 Rhythm Express Remote Cardiac Monitoring System
Classification Name: 870.2800, 870.1025
Electrocardiograph, Ambulatory, With Analysis Algorithm
Detector and Alarm, Arrhythmia,
Common or Usual Name: Ambulatory Cardiac Monitor
Device Panel: Cardiovascular
Regulatory Class: Class 2
Product Code: MLO, DSI

III. PREDICATE DEVICE

The RX-1 system is substantially equivalent in intended use and similar technological characteristics to the following devices: RX-1 Rhythm Express Remote Cardiac Monitoring System cleared under K183704, and PocketECG III - Medicalgorithmics Unified Arrhythmia Diagnostic System, cleared under K152550.

IV. DEVICE DESCRIPTION

The Rhythm Express RX-1 will be worn by patients for a period of time as prescribed by a physician, typically 1 day to 4 weeks, and will continuously monitor ECG. RX-1 will function in one of three modes: a) Mobile Cardiac Telemetry (MCT), b) Event Recorder (ER), and Wireless Holter (WH). The device will connect to standard ECG electrodes to capture 2 channel ECGs. An embedded algorithm processes the acquired ECG to detect arrhythmias, compress the ECG, and remove most in-band noise without distorting ECG morphology. RX-1 incorporates a cellular modem to communicate with the RS-1 Web Service.

The RX-1 device is not a life-supporting or life-sustaining system. Clinical judgment and experience are used to check and interpret the data.

V. INTENDED 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 device for arrhythmia analysis, reporting and signal measurements. The Rhythm Express device 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. 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.

VI. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The RX-1 system is substantially equivalent in intended use and similar technological characteristics of RX-1 system cleared under K183704.

Category	**Identical/ Different**	**RX-1**	**RX-1 predicate**	PocketECG III
510(k) Number		Pending	K183704	K152550
Classification Name	Identical	Electrocardiograph, Ambulatory, With Analysis Algorithm	Medical Mobile Cardiac Monitor	Arrhythmia Detector and Alarm
Product Code	Identical	MLO, DSI	DXH	DSI
Intended Use	Similar	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	The Rhythm Express remote cardiac monitoring system is intended for use by adult 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	1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of brady arrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease;

Category	Identical/ Different	RX-1	RX-1 predicate	PocketECG III
		a medical professional. The data received from the Rhythm Express device can be used by another device for arrhythmia analysis, reporting and signal measurements. The Rhythm Express device 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. 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.	and can be reviewed by a medical professional. The data received from the Rhythm Express device can be used by another device for arrhythmia analysis, reporting and signal measurements. The Rhythm Express device 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. 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.	2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath). 3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms. 4. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation). 5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring. 6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias. 7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.

Category	Identical/ Different	RX-1	RX-1 predicate	PocketECG III
				8. Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.
Delivered device includes, patient ECG cable - rechargeable battery -Wall Battery charger	Similar	Yes	Yes	Yes
Monitor functional blocks: ECG front end, DSP MCU, flash data storage, RF modem for data transmission, LCD screen, and keypad,	Similar	Yes	Yes	Yes
The server facilitates data communication with the device, provide data storage, and present the data for evaluation by a medical professional:	Similar	Yes	Yes	Yes

Category	**Identical/ Different**	**RX-1**	**RX-1 predicate**	PocketECG III
Device form factor: small, lightweight ambulatory cardiac monitors.	Similar	Yes	Yes	Yes
Wireless technology used to transmit data to server	Similar	LTE	LTE	GSM
Device is battery powered by a rechargeable Li-Ion battery	Similar	For 7 Days	For 7 Days	For 24 hours
using a server, can adjust device programming parameters such as pre-post recording times and auto-triggering configuration.	Similar	Yes	Yes	Yes
devices have keypad for manual event recordings and a user interface to indicate device status and mode of operation.	Similar	Yes	Yes	Yes
Device incorporate embedded ECG	Similar	Yes	Yes	Yes

Category	**Identical/ Different**	**RX-1**	**RX-1 predicate**	PocketECG III
analysis algorithm to auto-capture arrhythmia events between the signal acquisition point and the server.				
device has at least 2 ECG channels and 3-lead electrodes	Identical	Yes	Yes	Yes
Functional, Environmental and Electrical characteristics	Similar	Ambulatory use, charge from ac adapter 0-45C	Ambulatory use, charge from ac adapter 0-45C	Ambulatory use, charge from ac adapter 0-43C
Power Port	Different	Yes, USB port to charge the battery, cannot be connected during ECG recording, not used for data download.	Yes, USB port to charge the battery, cannot be connected during ECG recording, not used for data download.	No, Separate Battery charger to recharge removable battery pack.
Storage conditions	Similar	-25 to 45 C 10 to 95% RH	-25 to 45 C 10 to 95% RH	-20 to 60 C 15 to 93% RH

VII. PERFORMANCE TESTING

The following performance and safety tests have been passed successfully:

- IEC 60601-2-47:2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
- IEC 60601-1-1:2012 Ed. 3.1 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 62304:2015 Ed. 1.1 Medical Device Software – Software Life Cycle Processes.
- IEC 60601-1-2:2014 4th Edition, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance– Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-11:2015 Edition 1.1, 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.
- ANSI/AAMI TIR57:2015, Principles for medical device security—Risk management
- IEC 62366-1:2015 Edition 1.0, Medical devices – Part 1: Application of usability engineering to medical devices
- ANSI IEEE C63.27-2017 Evaluation of Wireless Coexistence
- Biocompatibility testing of patient contacting materials according to ISO 10993-1.
- Bench test results verify that RX-1 Monitor system can continuously record ECG signal, store ECG data in the device memory, and transmit manual or auto activated event recordings to the server via mobile network connection for evaluation by a medical professional. Test results verify that all requirements were met and that the RX-1 Monitor performs as designed.

VIII. SUBSTANTIAL EQUIVALENCE RATIONALE

The intended use, performance and technological characteristics of the RX-1 Monitor system compared to the named predicate device demonstrates that the RX-1 Monitor is substantially equivalent to the predicate.

IX. CONCLUSIONS

The analysis of the differences between RX-1 Monitor and the predicate device does not raise new questions of safety and effectiveness. Based on device performance test results, VivaQuant determines that the RX-1 Monitor system performs within its design specifications and is

substantially equivalent to the predicate devices.

The information in this 510(k), submission demonstrates that the RX-1 Monitor system is substantially equivalent to the predicate device.