October 18, 2017

Cardiomedix, Inc.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K172801
Trade/Device Name: ECG SENTINEL System
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: September 14, 2017
Received: September 18, 2017

Dear Mark Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172801

Device Name

ECG SENTINEL System

Indications for Use *(Describe)*

The SENTINEL 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 the ECG data and transfers the data to the Server. Upon detection by an ECG analysis algorithm at the Server the recorded cardiac activity is flagged for review by a medical professional.
The data received from the SENTINEL device can be used by another cleared device for arrhythmia analysis, reporting and signal measurements. The SENTINEL System is not intended to sound any alarms.

The device does not deliver any therapy, administer any drugs, provide interpretative or diagnostic statements or provide for any life support.

The SENTINEL System is for prescription use only.

User Population:

The SENTINEL is intended for use by adult or children when supervised by an adult.
The Sentinel is intended for use on adults and infants weighing more than 10 kg (22 lbs.).

Intended Operator Profile:

The SENTINEL is intended for home use. The review and analysis of data is intended for use by an appropriately trained medical practitioner.

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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TRADITIONAL 510(K) SUMMARY

Submitted by:	Cardiomedix, Inc.
Contact Person:	Zipora David President Cardiomedix, Inc. 1840 Oak Ave. Evanston, IL 60201 Ph: 847 869 0230 x100 Fax: 847 869 0850 Email: zipora@cardiomedix.com
Date of Summary:	October 17, 2017
Device Trade Name:	ECG SENTINEL System
Common or Usual Name:	Mobile Cardiac Monitor
Classification Name:	Telephone electrocardiograph transmitter and receiver (21 CFR 870.2920)
Class:	II
Product Code:	DXH
Predicate Device(s):	RhythmStar System (K141813)
Device Description:	Cardiomedix ECG SENTINEL System is a self-use, 2-lead ECG continuous acquisition and transmission system. The SENTINEL device connects via Bluetooth to a proprietary mobile phone-based, dedicated ECG acquisition, storage, and transmission application. The phone application facilitates the self-use of the device by providing messages and alerts for specific parameters. ECG SENTINEL System refers to the complete system with all component parts. SENTINEL refers to the monitoring device only. The SENTINEL data is continuously (long-term) transmitted by the phone to a designated server for storage, analysis, decision support, and response by a qualified and dedicated team. The SENTINEL is intended for use on patients with weighing more than 10 kg (22lbs.).

Intended Use:

The SENTINEL 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 the ECG data and transfers the data to the Server. Upon detection by an ECG analysis algorithm at the Server the recorded cardiac activity is flagged for review by a medical professional.
The data received from the SENTINEL device can be used by another cleared device for arrhythmia analysis, reporting and signal measurements. The SENTINEL System is not intended to sound any alarms.

The device does not deliver any therapy, administer any drugs, provide interpretative or diagnostic statements or provide for any life support.

The SENTINEL System is for prescription use only.

User Population:
The SENTINEL is intended for use by adult or children when supervised by an adult.
The Sentinel is intended for use on adults and infants weighing more than 10 kg (22 lbs.).

Intended Operator Profile:

The SENTINEL is intended for home use. The review and analysis of data is intended for use by an appropriately trained medical practitioner.

Technological Characteristics:

The ECG SENTINEL System component parts include:

- The SENTINEL monitoring device
- SENTINEL carrying pouch
- Smart phone with pre-installed dedicated application for SENTINEL ECG acquisition, storage and transmission
- Smart phone charger and cable
- Package of FDA Cleared ECG Electrodes
- Replacement batteries
- User guide

The SENTINEL monitoring device is a dedicated electronic device that records ECG and consists of

electronic circuit board, batteries, a plastic enclosure, and lead wires. The data transmission to the smart phone is via low energy Bluetooth transmission. The smart phone mobile device acts as in in-home communication relay, stores the data, and transfers the data via the WEB, using secure communication, to a call center. The Call Center provides a service platform to monitor, analyze, store, and report ECG data sent from the patient.

Performance Testing:

The ECG SENTINEL System conforms to the following performance and safety tests:

- AAMI/ANSI/IEC 60601-2-47:2012 – Medical Electrical Equipment – Part 2-47: Particular Requirements for the Basic Safety and Essential Performance of Ambulatory Electrocardiographic Systems
- AAMI/ANSI ES 60601-1:2005/(R) 2012 & A1:2012– Medical Electrical Equipment – Part 1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, mod). (General II (ES/EMC))
- IEC 60601-1-2, 4th Edition:2014-02 – 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 Edition 2.0 2015-01 – Medical Electrical Equipment – 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 62304 Edition 1.1 2015-06, medical device software - software life cycle processes.

Bench testing verifies that the ECG SENTINEL System can record ECG signal, store data, transmit data to the Call Center, where the data can be analyzed.

Test results confirm that the ECG SENTINEL System performs as designed.

Substantial Equivalence Rationale:

The ECG SENTINEL System is substantially equivalent to the RhythmStar System (K141813), manufactured by Rhythmedix, LLC.

The table, below, provides a side-by-side comparison between the ECG SENTINEL System and the RhythmStar System, with regards to the intended use, technology characteristics, principles of operation, and performance specifications. There are no fundamental differences between the ECG SENTINEL System and the predicate product, therefore supporting the final determination of substantial equivalence.

Substantial Equivalence Table

Device Attribute	ECG SENTINEL System Cardiomedix, Inc.	RhythmStar System Rhythmedix (K141813)	Substantial Equivalence Discussion
Intended use	The ECG SENTINEL 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 the ECG data and transfers the data to the Server. Upon detection by an ECG analysis algorithm at the Server the recorded cardiac activity is flagged for review by a medical professional. The data received from the SENTINEL device can be used by another cleared device for arrhythmia analysis, reporting and signal measurements. The	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 systems 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 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	The intended use is essentially the same. The difference is that the RhythmStar provides an arrhythmia detection algorithm on the data prior to it being sent to the Server, while the SENTINEL sends all the data to the server and performs arrhythmia analysis at the server. Both devices present the analyzed data to a medical professional for review.

	SENTINEL System is not intended to sound any alarms. The device does not deliver any therapy, administer any drugs, provide interpretative or diagnostic statements or provide for any life support. The SENTINEL System is for prescription use only.	system is not intended to sound any alarms. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide any life support. RhythmStar is for prescription use only	
Product Code	DXH	DXH	Same
Regulation Name and Number	Transmitters And Receivers, Electrocardiograph, Telephone. 21 CFR 870.2920	Same	
Patient population	Adults and Infants weighing more than 10Kg	Same	
Environment for Intended Use	Ambulatory, outpatient	Same	
Ambulatory ECG performance standards	IEC 60601-2-47:2012	Same	
System Description	3 off the shelf electrodes, patient pendant, cell phone, server, display and reporting	3 or 5 off the shelf electrodes, ECG device, server, display and reporting	The SENTINEL provides two channels of ECG, using 3 ECG leads, while the RhythmStar offers and optional 5 lead cable for 3 channels of ECG. In addition the RhythmStar has a GPRS transmitter built into the device to connect to the WEB and the SENTINEL uses an external Mobile Phone as a bridge to the WEB

Basic Technology	Analog ECG front-end, flash data storage, BT transmission to (Android) cell phone, cellular transmission to central server, arrhythmia analysis on central server	Analog ECG front-end together with an Cellular GPRS modem built into the device	The overall technology is the same, Analog ECG front-end to collect data that is sent to the WEB. The main technological difference is that the ECG device worn by the user transmits data via Bluetooth to a Cell Phone that then passes the data to the Server, while the RhythmStar contains the Cellular modem inside the device to directly send the data to the Server.
Energy Source	Two non-chargeable Zinc-Air hearing aid batteries	Li-Ion externally chargeable battery.	Both units require that the user replace the batteries periodically
AC Powered	No	No Uses an external battery charger to charge the battery.	
Channel Recording	2	2 or 3	
Bandwidth	0.5Hz to 35Hz	0.05Hz to 40Hz	Both units provide a standard monitoring bandwidth. The lower 0.05 provided by the RhythmStar is typically required for S-T measurements, but neither units provides S-T measurements
Common-mode rejection ratio (CMRR)	Meets IEC60601-2-47 standards	same	
Sampling Rate	Minimum 125 typical 250 Hz	same	

Patient Cable	Built-in 3 lead cable	Detachable 3 or 5 lead cable	
Lead off Detection	Yes	Yes	
Accelerometer	No	Yes	
Data Transmission	Wireless, via mobile network using Android phone	Same	
Overall System Design	PEMS and Software	PEMS and Software	
Sterile	non-sterile	Same	
Single Use	No	Same	
Arrhythmia Detection Algorithm	On server, only.	In Device	
Alarms	None	Same	
User Event Trigger	Continuous Recording and Transmission	Algorithm based or user triggered transmission	Continuous Transmission allows all events to be seen by the medical staff.
Battery life	Typically 5 days	72 hours (3 Days)	
Dimensions	7cm x 5cm x 1.5cm	10cm x 6.6cm x 1.3cm	
Weight (with battery)	85 gm	90 gm	
Operating temperature	10 °C to 45 °C	0 °C to 40°C	
Transport and storage temperature	-25 °C to 70 °C	-25 °C to 70 °C	
Relative humidity	10 % to 95 %, without condensation	10 % to 95 %, without condensation	

SUBSTANTIAL EQUIVALENCE ANALYSIS

Similarities between the ECG SENTINEL System and the RhythmStar System:

1. Both devices are small, lightweight ambulatory cardiac monitors, intended for the same patient population.
2. Both devices have at least 2 channels and 3 ECG electrodes.
3. The overall technology is the same, with analog ECG front-end to collect data that is sent to the WEB.
4. RhythmStar has a GPRS transmitter built into the device to connect to the WEB and the ECG SENTINEL System uses an external Mobile Phone as a bridge to the WEB.
5. Both devices are battery powered. The RhythmStar System utilizes a rechargeable Li-Ion battery, while the ECG SENTINEL System used replaceable Zinc-Air batteries.
6. Both units provide the standard monitoring bandwidth.

There are known differences between the ECG SENTINEL System and the RhythmStar System that do not impact the safety or effectiveness:

1. RhythmStar provides an arrhythmia detection algorithm on the data prior to it being sent to the server, while the ECG SENTINEL device sends all the data to the server and performs arrhythmia analysis at the server. Both devices present the analyzed data to a medical professional for review.
2. The ECG SENTINEL System transmits data via Bluetooth to a Cell Phone that then passes the data to the server, while the RhythmStar contains the Cellular modem inside the device to directly send the data to the server. Both devices utilize a mobile network to deliver data to the server.
3. The RhythmStar System incorporates an algorithm based or user triggered event trigger. The ECG SENTINEL System provides continuous recording and transmission of the data with an ECG analysis algorithm at the server. Both devices provide the ability for detection of arrhythmia events and activity identified for subsequent review by a medical professional.

The analysis of the differences between the ECG SENTINEL System and RhythmStar system do not raise any new questions of safety and effectiveness. Both devices have the same or very similar functional, environmental, and electrical characteristics. The ECG SENTINEL System is safe, effective, performs within the design specifications, and is substantially equivalent to the predicate, RhythmStar System.

Conclusion: Based on the non-clinical testing conducted, the ECG SENTINEL System is considered safe, and is effective when used as indicated. Therefore, ECG SENTINEL System is substantially equivalent to the legally marketed predicate device, RhythmStar System (K141813).