DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 12, 2015

Ross Medical Technology, Inc.
Alexander Chiu
President
82 E. Allendale Road, Suite 8a
Saddle River, New Jersey 07458

Re: K142352
Trade/Device Name: CardiacLinx
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: DSI, DPS, DQK
Dated: February 12, 2015
Received: February 13, 2015

Dear Alexander Chiu,

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.

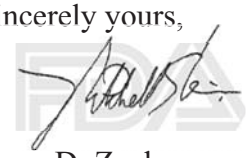
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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 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 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 yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K142352

Device Name: CardiacLinx

Indications for Use:

The following Indications for Use are identified for the CardiacLinx device:

1. MCT Mode: For use on adult patients who experience transient or non-transient symptoms that may suggest cardiac arrhythmias. The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible notification when Ventricular Fibrillation/Flutter, Atrial Fibrillation/Flutter, Pause (Asystole), Bradycardia, or Tachycardia occurs.

2. Holter Mode: For use on adult patients experiencing palpitations, syncope, pre-syncope, dizziness, arrhythmia, bradycardia, tachycardia, angina, ischemia and paced ECG.

3. Multi-Lead (Resting EKG) Mode: For use on adult patients for acquiring, storing and viewing/printing of up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the patient's body.

4. The intended use locations for CardiacLinx are in a physician's office, hospital or rehabilitation facilities, patient's home, or similar use areas. It is intended to be used by or on the order of a physician or similarly qualified health care professional.

5. For general hospital or clinical use by medical professionals whenever an assessment of a patient's ambulatory ECG data is required. Allows for a trained physician or health care professional to download and analyze the data for review and to produce printed reports. This will enable the evaluation of arrhythmias, ischemic attacks, reporting of PQRST intervals, clinical and epidemiological research studies, evaluation of a patient response after resuming occupational or recreational activities (e.g., after myocardial infarction or cardiac surgery), and/or evaluation of patients with pacemakers. CardiacLinx is only available for use upon the order of a physician or other related licensed medical professional.

6. For use under the supervision of a qualified physician trained in ECG interpretation to record the electrical activity of the heart for the purpose of correlating resultant waveforms with the health of the heart muscle tissue structures.

Contraindications for Use:

CardiacLinx is not indicated for use by patients with potentially life-threatening arrhythmias who require inpatient monitoring and/or patients whom the attending physician recommends hospitalization.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

For Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5: 510(k) Summary

Submitter

Company:	Ross Medical Technology, Inc.
Address:	82 E. Allendale Road, Suite 8A Saddle River, NJ 07458
Contact:	Dr. Alexander Chiu
Phone:	973-874-9711
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Date Prepared:	August 20, 2014

Device

Trade Name:	CardiacLinx
Common Name:	Arrhythmia detector and alarm
Classification:	Detector and alarm, arrhythmia
Product Code:	DSI, DPS, DQK
Regulation:	870.1025, 870.2340, 870.1425
Class:	II, Special Controls

Predicate Devices

The following FDA cleared devices have been selected by Ross Medical Technology, Inc. ("RMT") as predicate devices of CardiacLinx in order to demonstrate substantial equivalence:

1. Applied Cardiac Systems Cardiac Outpatient Real-time ECG (CORE™) (herein, "The CORE"), cleared by the FDA under 510(k) number K103706; Product Classification Code DSI; Regulation 870.1025.

2. Pulse Biomedical, Inc. ("PBI") QRS Card™ S-T Segment Analysis Patient Monitoring System Modification (Device Trade Name "QRS Card BT"), cleared by the FDA under 510(k) number K100813; Product Classification Code DPS; Regulation 870.2340.

3. PBI Cardiology Suite 4.0™ Ambulatory ECG Analysis System (herein, "PBI Cardiology Suite"), cleared by the FDA under 510(k) number K042799; Product Classification Code DQK; Regulation 870.1425.

4. Cardiac Science Corporation Atria 3100/6100 (herein, "Atria 3100/6100"), cleared by the FDA under 510(k) number K060167; Product Classification Code DPS; Regulation 870.2340.

Device Description

The CardiacLinx System is a continuous real-time ECG monitor and arrhythmia detector. It is a multipurpose device designed with the ability to collect ECG data from the patient in order to perform:

1. 2-lead Mobile Cardiac Outpatient Telemetry (MCT) for up to 30 days;
2. 24 hour or longer 3-lead Holter monitoring; or
3. Resting 12-lead ECG with interpretation.

The ambulatory device may be used on an outpatient basis with remote clinician data analysis whenever it is required to assess a patient's ambulatory ECG data (MCT and Holter modes), as well as for use within the physician office setting by the medical professional (resting 12-lead mode).

The product consists of monitoring equipment worn by the patient that transmits all asymptomatic and symptomatic events to a central computer monitoring center in the outpatient setting. The central computer monitoring center is equipped with personal computers running CardiacLinx System software intended for use only by qualified medical professionals and their staff.

CardiacLinx is comprised of three (3) main software components developed by Ross Medical Technology, consisting of:

1. *The Ross Medical Technology* ***PMD Software*** that can be run on a Personal Mobile Device ("PMD") with Bluetooth capabilities and a built-in cellular modem. The Personal Mobile Device is configured to process and transmit signals from an FDA cleared patient-worn ECG Monitor (also with Bluetooth capabilities);
2. *The Ross Medical Technology* ***MCT Server Software*** that can be run on a central server that receives, interprets (using embedded algorithms), and stores the ECG data from the PMD Software; and
3. *The Ross Medical Technology* ***MCT Client Software*** that can be run at a central computer monitoring center attended by trained medical professionals who can view the ECG data and interpretations.

In addition to the three main software components manufactured by Ross Medical Technology, CardiacLinx includes third party components that are necessary to complete the functionality of the device. These third party components are:

1. An FDA cleared patient-worn ECG Monitor;
2. A Personal Mobile Device with Bluetooth capabilities and built-in cellular modem; and
3. Two embedded ECG Interpretation Algorithms found in other FDA cleared ECG analysis devices.

The CardiacLinx device integrates these third party components with RMT's proprietary software.

Principles of Operation

The CardiacLinx System operates as follows:

1. Sensors attached to the patient's chest capture the heart signals of the patient.
2. The ECG Monitor connected to the sensors converts the heart signals to data and transmits it to the Bluetooth enabled Personal Mobile Device.
3. The PMD Software embedded on the Personal Mobile Device transmits the ECG data to the MCT Server Software via 3G, 4G, or Wi-Fi cellular networks.
4. The MCT Server Software interprets the ECG data using the embedded ECG Interpretation Algorithms and stores both the ECG data and interpretations in a database.
5. Technicians and/or physicians can monitor the heart signals of the patients in real-time using the MCT Client Software. The automatic interpretations can be viewed to assist in diagnosis and treatment plans.
6. The MCT Client Software is also used to manage Patients, Prescriptions, and Users of the System, as well as to produce Prescription Reports and MCT and Holter export records, if needed.

ECG data from all 12 leads are transmitted to the CardiacLinx MCT Server Software at all times while a prescription is active. Using this data, the MCT Client Software can produce three different final reports. These three reporting options can be chosen by the CardiacLinx MCT Client Software user, and represent the three different configurations below:

- 3 wire, ambulatory, grip electrode cable with signals from 1 or 2 leads, representing *MCT Mode*
- 5 wire, ambulatory, grip electrode cable with signals from 3 leads, representing *Holter Mode*
- 10 wire, resting, grip electrode cable with signals from 12 leads, representing *Resting Mode* (8 channels; derived leads III, aVF, aVR, aVL)

There is no need to change the electrode wire configuration on the patient; all 10 wires will remain connected to the patient and all data will continuously transmit to the CardiacLinx MCT Server Software. The MCT Client Software user simply chooses which report to generate and has all data necessary to produce any report. For Resting Mode, although it is not clinically required for the Patient to be "resting", it is the nonetheless the User's (or medical provider's, or both) responsibility to determine if the patient is in the proper state to allow for a clinically acceptable ECG signal for a ten (10) second time frame.

Intended Use

The CardiacLinx System is intended for outpatient use with remote clinician data analysis as well as for use within the physician office setting by the medical professional, or whenever it is required to assess a patient's ambulatory ECG data. This product allows a trained physician or healthcare professional to analyze continuous and intermittent measurements of heart rate and rhythm over several days. All asymptomatic and symptomatic events are transmitted to a central computer in the outpatient setting. This will enable the evaluation and documentation of arrhythmias, ischemic attacks, PQRST intervals, clinical and epidemiological research studies, and/or the evaluation of a patient's response after resuming occupational or recreational activities. The MCT, Holter, and resting 12-lead ECG modes are intended for use on adult patients only on the order of a physician or related licensed medical professional.

Indications for Use

The following Indications for Use are identified for the CardiacLinx device:

1. MCT Mode: For use on adult patients who experience transient or non-transient symptoms that may suggest cardiac arrhythmias. The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible notification when Ventricular Fibrillation/Flutter, Atrial Fibrillation/Flutter, Pause (Asystole), Bradycardia, or Tachycardia occurs.

2. Holter Mode: For use on adult patients experiencing palpitations, syncope, pre-syncope, dizziness, arrhythmia, bradycardia, tachycardia, angina, ischemia and paced ECG.

3. Multi-Lead (Resting EKG) Mode: For use on adult patients for acquiring, storing and viewing/printing of up to twelve (12) leads of patient ECG waveforms through surface electrodes adhered to the patient's body.

4. The intended use locations for CardiacLinx are in a physician's office, hospital or rehabilitation facilities, patient's home, or similar use areas. It is intended to be used by or on the order of a physician or similarly qualified health care professional.

5. For general hospital or clinical use by medical professionals whenever an assessment of a patient's ambulatory ECG data is required. Allows for a trained physician or health care professional to download and analyze the data for review and to produce printed reports. This will enable the evaluation of arrhythmias, ischemic attacks, reporting of PQRST intervals, clinical and epidemiological research studies, evaluation of a patient response after resuming occupational or recreational activities (e.g., after myocardial infarction or cardiac surgery), and/or evaluation of patients with pacemakers. CardiacLinx is only available for use upon the order of a physician or other related licensed medical professional.

6. For use under the supervision of a qualified physician trained in ECG interpretation to record the electrical activity of the heart for the purpose of correlating resultant waveforms with the health of the heart muscle tissue structures.

Contraindications for Use

CardiacLinx is not indicated for use by patients with potentially life-threatening arrhythmias who require inpatient monitoring and/or patients whom the attending physician recommends hospitalization.

Comparison of Technological Characteristics

A comparison of the technological characteristics between the CORE predicate device and the CardiacLinx device will be summarized here. Additional comparisons and further detail is provided in Section 12 of this 510(k) Premarket Notification.

In regards to the CORE, RMT makes the following observations and conclusions in comparing the technology and performance characteristics of the two devices.

1. The CORE offers multiple electrode configurations, whereas the CardiacLinx device is intended to have all 10 electrodes attached to the patient regardless of mode. This does not affect safety and effectiveness when compared to the CORE.
2. CardiacLinx does not have a manual trigger.
3. ECG Algorithms differ between two devices, with CardiacLinx appearing to offer a more robust library of ECG interpretations.
4. Physical differences between the two devices are inconsequential.
5. Both devices can operate within their Intended Use based on performance specifications.

RMT believes that the CardiacLinx device has essentially the same technology and performance characteristics as the CORE and is therefore substantially equivalent the CORE.

Performance Data

The following performance data are provided in support of the substantial equivalence determination made by Ross Medical Technology, Inc. for its CardiacLinx device.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation is provided pursuant to FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (the "Software Guidance"). As discussed in Section 16 of the 510(k) Premarket Notification, the CardiacLinx System software was found to have a "Moderate" level of concern based on FDA's guidance document. A failure or latent flaw in the CardiacLinx System's software could directly result in a minor injury to the Patient. As a result, the software documentation provided in the 510(k) Premarket Notification will be commensurate with this Moderate Level of Concern classification as outlined in the Software Guidance.

Electrical Safety and Electromagnetic Compatibility

Ross Medical Technology, Inc. is citing the electrical safety and electromagnetic compatibility (EMC) testing already performed on the FDA cleared components of the CardiacLinx System. These components of the CardiacLinx System are in compliance with the following standards for electrical safety and electromagnetic compatibility:

1. ANSI/AAMI EC11:1991/(R) 2001, Diagnostic electrocardiograph devices.
2. EN 60601-1:2006; Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
3. EN 60601-1-2:2007; Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
4. EN 60601-2-25:1995; Medical electrical equipment – Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs.

Section 17 of the 510(k) Premarket Notification discusses electrical safety and EMC in more detail.

Additional Testing

To further demonstrate the effectiveness of the CardiacLinx System, RMT conducted additional tests that go beyond the testing discussed above. Table 5.1 below summarizes the additional tests that RMT performed on the CardiacLinx System.

Through the FDA's Pre-Submission process (Q130826), and documented in the approved meeting minutes (Q130826/A001), it was determined that additional testing may be done for the expanded indication for use of the FDA cleared ECG Monitor to include the ambulatory and home environment. RMT conducted the Ambulatory and Home Environment Interference test (summarized below) to determine any clinically significant differences in ECG interpretation when

the CardiacLinx system is used in the ambulatory and home environment. Special consideration in this test was given to test clinically significant artifacts from electronic sources and motion.

Table 5.1: Additional Testing Performed

Test Name	RMT Document Ref.	Purpose of Test	Results of Test	Comments
Ambulatory and Home Environment Interference	INTE-RMT-0201	To test whether ambulatory and home environments would produce a clinically significant change in ECG interpretation.	Device performed as intended. 100 out of 100 samples in each test (1,000 out of 1,000 total samples) showed identical clinical interpretation from two independent board certified physicians.	Test Report provided in Section 18
Data Transmission	SWTP-RMT-0205	Test reliability of data transmission from PMD to MCT Server Software.	97.00% of data packets received by the MCT Server Software between 0 and 5 seconds.	Test Report provided in Section 18

Substantial Equivalence Conclusion

The CardiacLinx device essentially has the same intended use, operating principles, and technical characteristics as the predicate devices. The FDA cleared components of the CardiacLinx System are unchanged. Standards testing cited by RMT is substantially equivalent to standards testing performed on the predicate devices, and in some cases identical.

Any differences in Intended Use, Indications for Use, technology, performance, or testing between the predicate devices and CardiacLinx are adequately explained and justified. These differences do not pose additional concerns related to the safety and effectiveness of the CardiacLinx device. Supplemental tests and information is provided in the 510(k) Premarket Notification to sufficiently justify this claim, with specific attention brought to Sections 16, 17, and 18 of this Premarket Notification. In Sections 17 and 18, concerns about using the ECG Monitor in the ambulatory and home environment are addressed and alleviated.

Based on the comparisons made to the predicate devices and the supplemental data provided, the CardiacLinx device is substantially equivalent to the predicate devices.