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

June 26, 2017

CardioLogs Technologies
% Michael Daniel
President
Daniel & Daniel Consulting, LLC
34 Jones Lane
Gardnerville, Nevada 89460

Re: K170568
Trade/Device Name: CardioLogs ECG Analysis Platform
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: March 10, 2017
Received: March 13, 2017

Dear Michael Daniel:

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,

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

Enclosure

6. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(K) Number: K170568

Device Name

CardioLogs ECG Analysis Platform

° Indications for Use *(Describe)*

The CardioLogs ECG Analysis Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in subjects over 18 years of age. The product supports downloading and analyzing data recorded in compatible formats from any device used for the arrhythmia diagnostics such as Holter, event recorder, 12 lead ambulatory ECG devices, or other similar devices when assessment of the rhythm is necessary. The Cardiologs ECG Analysis Platform can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems, such as an ECG management system. The Cardiologs ECG Analysis Platform provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. The Cardiologs ECG Analysis Platform is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.

The product can be integrated into computerized ECG monitoring devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device.

Cardiologs ECG Analysis Platform interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

7. Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K170568

Applicant Information:

Date Prepared: February 24, 2017

Name: Cardiologs Technologies
Address: Campus des Cordeliers, 15 rue de l'École de Médecine, 75006 Paris, France

Contact Person: Michael A Daniel, Consultant
madaniel@clinregconsult.com
Mobile Number: (415) 407-0223
Office Number: (775) 392-2970
Facsimile Number: (610) 545-0799

Device Information:

Device Trade Name:	CardioLogs ECG Analysis Platform
Common Name:	CardioLogs ECG Analysis Platform
Classification Name(s):	Electrocardiograph / Programmable Diagnostic Computer
Product Code/ Regulation:	DQK, DPS 21 CFR 870.1425 / 21 CFR 870.2340
Classification:	Class II

Predicate Device:

Monebo Automated ECG Analysis and Interpretation Software Library (K062282)

In compliance with FDA Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" we are including the following as reference devices:

Reference Devices:

TM eCloud ECG Analysis System (K142349)

7.1. Subject Device Description

CardioLogs ECG Analysis Platform is made up of:

- An interface which provides tools to measure, analyze and review numerous ECGs;
- An automated proprietary ECG interpretation support algorithm which measures and analyzes ECGs to provide physicians supportive information for ECG analysis.

CardioLogs ECG Analysis Platform can be accessed through a network connection/wireless device when the electrocardiograph allows for digital ECG upload, or locally (stand-alone algorithm).

CardioLogs ECG Analysis Platform is only intended to analyze recordings performed on adults (over the age of seventeen).

CardioLogs ECG Analysis Platform works in the following sequence:

1. Upload of digital ECG file to CardioLogs' secured hosting databases (for health data i.e. HIPAA compliant);
    - Manual upload: via the web-interface which allows the selection of files to upload on the evaluating user's computer
    - Direct upload: with no manual intervention, in the specific cases where the user's hardware is already connected to the CardioLogs' Application Programming Interface (or API): the ECG is automatically sent to CardioLogs' servers.
2. Processing of the uploaded ECG file;
3. Analysis of the uploaded ECG performed by CardioLogs' proprietary algorithm, which labels the ECG;
    - Delineation (detection of at least P waves, QRS complexes and T waves on the ECG signal). The output format is a sequence of elements "wave type/start time/ end time";
    - Abnormality labels: the algorithm provides probability scores on a predefined set of abnormality labels (multi-label classification);
4. CardioLogs ECG Analysis Platform displays the resulting analysis, along with the original ECG signal and a variety of tools (ruler, zoom, etc.). Results are made available either on the CardioLogs interface if the user's hardware allows for digital ECG upload, or on an API in cases where the service is available as part of a package with an ECG machine;
5. CardioLogs ECG Analysis Platform then allows for editing and/or confirmation of the measurements and parameters by the analyzing physician.

The resulting information is stored on a secured database.

7.2. Subject Device Indications for Use

The CardioLogs ECG Analysis Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in subjects over 18 years of age. The product supports downloading and analyzing data recorded in compatible formats from any device used for the arrhythmia diagnostics such as Holter, event recorder, 12 lead ambulatory ECG devices, or other similar devices when assessment of the rhythm is necessary. The Cardiologs ECG Analysis Platform can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems, such as an ECG management system. The Cardiologs ECG Analysis Platform provides ECG signal processing and analysis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. The Cardiologs ECG Analysis Platform is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.

The product can be integrated into computerized ECG monitoring devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device.

Cardiologs ECG Analysis Platform interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

7.3. Predicate and Reference Device and Subject Device Comparison

Table 7.3.1 compares the features of the CardioLogs ECG Analysis Platform to the predicate device.

Feature	Cardiologs ECG Analysis Platform	Monebo Automated ECG Analysis and Interpretation Software Library
Heart rate determination for non-paced adult	Yes	Yes
QRS Detection	Yes	Yes
Non-paced arrhythmia interpretation for adult patients	Yes	Yes
Non-paced ventricular arrhythmia calls	Yes	Yes
Intervals measurements	Yes	Yes
Ventricular ectopic beat detection	Yes	Yes
Patient Population	Adult	Adult

Table 7.3-1. Comparison between predicate and subject device features.

Comparison of Subject Device to Predicate Device:

	Subject Device	Predicate Device	Comparison to predicate device
Device Name	CardioLogs ECG Analysis Platform	Monebo Automated ECG Analysis and Interpretation Software Library	N/A
Manufacturer	Cardiologs Technologies	Monebo Technologies, Inc.	N/A
510(k) #	TBD	K062282	N/A
Regulation Number	21 CFR 870.2340	21 CFR 870.2340	Same
Class	II	II	Same
Device Class/Name	Electrocardiograph	Electrocardiograph	Same
Product Code	DQK, DPS	DPS	DPS is the same
Level of Concern	Moderate	Moderate	Same
Indication for Use	Refer to Section 7.2	Refer to predicate device labeling.	Both devices are intended for the same use.

	Subject Device	Predicate Device	Comparison to predicate device
Fundamental scientific technology	The CardioLogs ECG Analysis Platform consists of: - An interface which provides tools to measure, analyze and review numerous ECGs coded in java language under the Angular and D3.js frameworks; - An automated proprietary ECG interpretation support algorithm which measures and analyzes ECGs to provide supportive information for ECG diagnosis, written in Python language. This application can be accessed through an Internet connection and a web browser, or is directly connected to the CardioLogs' Application Programming Interface (API)	The predicate device is a collection of callable functions that have been complied into machine code or IDL code of the computer on which they execute. The predicate device consists of a basic application for viewing, analyzing and annotating ECG data, and a callable object library built on the Microsoft .Net framework. An application software can be written to invoke some or all the functions in an object library. The library can be accessed through an Application program Interface (API) as a callable function. This allows the library to be used as an accessory to an ECG management application or as a stand-alone product.	The CardioLogs ECG Analysis Interface and the predicate device both consists of - a user's interface for viewing, analyzing and annotating ECG data - an algorithm - an API to access to the algorithm An object library is a type of algorithm architecture, they are coded in the 2000's. The languages and frameworks used to develop the software are different. The CardioLogs ECG Analysis Platform is coded with the modern tools. The subject device is accessible through the Internet, while the predicate device is installed on the user's hardware. CardioLogs ECG Analysis Platform therefore does not present any major technological innovations compared to predicate device. However, to further demonstrate the non-innovative technology used by the predicate devices, its technology is compared to a reference device.

Table 7.3-2. Comparison between subject and predicate device.

Difference in Fundamental Scientific Technology:

The Predicate device was designed for technology that was available in the early 2000's, i.e. software program running on a hardware-based platform. With the advancement of cloud

computing, the Subject device incorporates a logical update to that technology as a software program running on a cloud-based software platform. Indeed, the Subject devise is cloud-based and available online, implying different cybersecurity, safety and effectiveness question. Therefore, the Subject device is also compared to a Reference device (the previous Predicate device): the TM eCloud ECG Analysis System. The TM eCloud ECG Analysis System is intended to provide an interpretation of up to 12-channel ECG in all situations including resting and ambulatory ECG including Holter, cardiac event, and mobile cardiac telemetry. It is designed for acquisition, analysis, edit, review, report and storage of all ECG and multi-parameter data.

Although the Predicate device slightly differs from the Subject device related to the operating technology platform, there are several examples, one being the Reference device, that use cloud based computing for ECG data analysis. This fact, in combination with identification of hazards and appropriate risk controls related to this difference, we conclude that this difference in technology platform has no impact on the safety or efficacy of the Subject device.

Comparison to Reference Device:

	Subject Device	**Reference Device**	**Comparison to Reference device**
Device Name	CardioLogs ECG Analysis Platform	TM eCloud ECG Analysis System	N/A
Manufacturer	Cardiologs Technologies	Telemed Solutions, Inc.	N/A
510(k) #	TBD	K142349	N/A
Regulation Number	21 CFR 870.1425	21 CFR 870.1425	Same
Class	II	II	Same
Device Class/Name	Programmable Diagnostic Computer	Programmable Diagnostic Computer	Same
Product Code	DQK	DQK, KRE, MLO, DPS, DXH, OUG	DQK is the same

	Subject Device	Reference Device	Comparison to Reference device
Fundamental scientific technology	The Cardiologs ECG Analysis Platform consists of a (1) server-side, application Platform as a Service (PaaS) cloud based system, and (2) a client-side application website. The (1) server-side, application PaaS component collects, stores, performs arrhythmia analysis on ECG uploads, and transfers data to and from the client-side application. The (2) client-side application allows the users to review ECG, edit the analysis results produced by the (1) server-side, application PaaS component. The users may upload ECG to the ECG Analysis Platform via the API (REST web service) from any computer equipment, or, in the specific cases where the user's hardware is already connected to the CardioLogs' Application Programming Interface (or API), the ECG is automatically sent to CardioLogs' servers.	The TM eCloud ECG Analysis System consists of a (1) server-side, application Platform as a Service (PaaS) cloud based system, a (2) desktop client-side application, and (3) a web-based Physician Portal website. The (1) server-side, application PaaS component collects, stores, performs arrhythmia analysis on ECG uploads, and transfers data to and from the client-side application. The (2) desktop client-side application is a workstation system which allows technicians to review ECG, edit the analysis results produced by the (1) server-side, application PaaS component, and generate reports for the ECG study. The edited results and reports are uploaded to the (1) server-side, application PaaS component. It also allows notifications and updates to (3) Physician Portal website. The users may upload ECG to the TM eCloud ECG Analysis System via a cellular network, REST web service, or FTP from any computer or cellular equipment.	Both the devices consists of a server-side, application Platform as a Service (PaaS) cloud based system, and a client-side application website, that works the same way. The only difference is that the reference device user interface is installed on the user's hardware while the subject device user interface is also online. CardioLogs ECG Analysis Platform therefore does not present any major technological innovations compared to the reference device

Table 7.3-3. Comparison between subject and reference device

7.4. Testing Completed

Tests have been performed in compliance with the following recognized consensus standards:

- AAMI ANSI IEC 62304 2006 - Medical device software - Software life-cycle processes
- IEC EN 60601-2-25 Edition 2.0 2011-10 - Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs-
- IEC 62366-1 Edition 1.0 2015-02 - Medical devices - Application of usability engineering to medical devices.
- AAMI ANSI EC57:2012 - Testing and Reporting Performance Results of Cardiac Rhythm And ST-Segment Measurement Algorithms

- AAMI ANSI IEC60601-2-47:2012 - Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems

Testing described in this 510(k) consisted of verification of all design input requirements and product specifications. All clinical input requirements were validated against a gold standard.

No residual anomaly appeared during verification and software validation tests.

General usability tests, analyzing the users' ability to import, display, store, analysis, distribute, and manage ECG data, were performed and met all requirements. All software validation testing was completed successfully and met all requirements.

7.5. Summary

Based upon the Intended Use, Indications for Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the CardioLogs ECG Analysis Platform has been shown to be substantially equivalent to the cited predicate and very similar to the cited reference devices.