January 13, 2022

Cardiologs Technologies
Arezou Azar
VP, Regulatory Affairs and Quality Assurance
136 Rue Saint Denis
Paris, ILE DE FRANCE 75002
France

Re: K212112
Trade/Device Name: Cardiologs Holter Platform
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK

Dear Arezou Azar:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 18, 2021. Specifically, FDA is updating this SE Letter as an administrative correction to the Indications for Use statement.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jennifer Shih Kozen, OHT2: Office of Cardiovascular Devices, 301-796-5813, Jennifer.Shih@fda.hhs.gov.

Sincerely,

Jennifer W. Shih -S

Jennifer Shih 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

November 18, 2021

Cardiologs Technologies
Arezou Azar
VP, Regulatory Affairs and Quality Assurance
136 Rue Saint Denis
Paris, ILE DE FRANCE 75002
France

Re: K212112
Trade/Device Name: Cardiologs Holter Platform
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK
Dated: October 18, 2021
Received: October 18, 2021

Dear Arezou Azar:

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 and Part 809); 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 Shruti N. Mistry -S

Jennifer Shih Kozen
External Heart Rhythm and Rate Team
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)*
K212112

Device Name
Cardiologs Platform

Indications for Use *(Describe)*

The Cardiologs Platform (Also known as Cardiologs ECG Analysis Platform) is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in the adult and pediatric population. 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 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 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 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 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)

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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.

Applicant Information:

Date Prepared:	November 18, 2021
Name:	Cardiologs Technologies
Address:	136 Rue Saint Denis, 75001 PARIS
Primary Contact Person:	Arezou Azar, PhD.
	arezou@cardiologs.com
Telephone Number:	+1 650-804-0285

Device Information:

Device Trade Name:	Cardiologs Holter Platform
Common Name:	Cardiologs Holter 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:
Cardiologs ECG Analysis Platform (K170568)

I. Subject Device Description

Cardiologs Holter Platform is a software only medical device with the following components 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 Holter Platform can be accessed through a network connection/wireless device when the electrocardiograph allows for digital ECG upload, or locally (stand-alone algorithm).

Cardiologs Holter Platform works in the following sequence:

I. 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.

II. Processing of the uploaded ECG file;

III. 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);

IV. Cardiologs Holter 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

V. Cardiologs Holter 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.

II. Subject Device Indications for Use

The Cardiologs Holter Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in the adult and pediatric population. The product supports downloading and analyzing data recorded in compatible formats from any device used for 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 Holter 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 Holter 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 Holter 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 Holter 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.

III. Predicate and Subject Device Comparison

The table below compares the features of the Cardiologs Holter Platform to the predicate device.

Feature	Cardiologs ECG Analysis Platform (K170568)	Cardiologs Holter Platform (Subject device)
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 & Pediatric

Table 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 Holter Platform	Cardiologs ECG Analysis Platform	Same
Manufacturer	Cardiologs Technologies	Cardiologs Technologies	Same
510(k) #	TBD	K170568	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	DQK, DPS	Same
Level of Concern	Moderate	Moderate	Same
Intended Use	Assessment of ECG arrhythmias	Assessment of ECG arrhythmias	Same
Indications for Use	The Cardiologs Holter Platform is intended for use by qualified healthcare professionals for the assessment of arrhythmias using ECG data in the adult and pediatric population. The product supports downloading and analyzing data recorded in compatible formats from any device used for the arrhythmia	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	The subject device is indicated for pediatric as well as adult patients.

	diagnostics such as Holter, event recorder, 12 lead ambulatory ECG devices, or other similar devices when assessment of the rhythm is necessary. The Cardiologs Holter 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 Holter 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 Holter 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 Holter 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	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, 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	

	background, clinical history, symptoms, and other diagnostic information.	conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.	
Fundamental scientific technology	The Cardiologs Holter 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 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).	Same

Table 2 - Comparison between subject and predicate device

IV. 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 anomalies 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 on the previously cleared version of the software and met all requirements. The minimal changes to the software implemented for the subject device have been confirmed to have no impact on usability. Consequently, the previous usability testing is representative of the current version of software and no additional usability testing is required. All software validation testing was completed successfully and met all requirements.

V. Summary

Based upon the Intended Use, Indications for Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the Cardiologs Holter Platform has been shown to be substantially equivalent to the cited predicate.