June 23, 2023

AccurKardia, Inc.
% Adrienne Lenz
Principle Medical Device Regulation Expert
Hyman, Phelps & McNamara, PC
700 Thirteenth Street, N.W., Suite 1200
Washington, District of Columbia 20005-5929

Re: K223013
Trade/Device Name: AccurECG® Analysis System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK
Dated: May 26, 2023
Received: May 26, 2023

Dear Adrienne Lenz:

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 Shruti N. Mistry -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

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)*

K223013

Device Name

AccurECG® Analysis System

Indications for Use *(Describe)*

The AccurECG Analysis System is intended for use by qualified healthcare professionals in the assessment of a patient's recorded ambulatory ECG data. Analysis results are provided in a standard report for review and printing.

The System provides single-lead analysis on a beat-by-beat basis, Ventricular Ectopic Beat and Supraventricular Ectopic Beat detection, heart rate measurement, and rhythm analysis. The AccurECG Analysis System is compatible with ECG recordings taken with silver/silver chloride (Ag / AgCl) electrodes (wet leads).

The AccurECG Analysis System is not for use in life-supporting or sustaining systems or ECG monitor and alarm devices. The System is not intended to be used with cardiac telemetry monitors.

The AccurECG Analysis System's automated interpretation results are not intended to be the sole means of diagnosis. The AccurECG Report is an adjunct intended to facilitate health care decision making in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information to arrive at a diagnostic conclusion.

The AccurECG Analysis System does not interface with data management systems or hardware and is device independent.

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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SECTION 5 : 510(k) Summary

5.1 Applicant/Submitter

Company Name	:	AccurKardia, Inc.
Street Address	:	101 Avenue of the Americas, FL 8
City	:	New York
State	:	New York
Zip Code	:	10013
Phone Number	:	646-334-5728

5.2 Contact Person

Full Name	:	Juan C. Jiménez
Phone	:	646-334-5728

5.3 Correspondent Information

Full Name	:	Juan C. Jiménez
Phone	:	646-334-5728

5.4 Date of Preparation

Date of Preparation	:	05/26/2023

5.5 Device Information

Device Name	AccurECG® Analysis System
Model Number	

Common Name	ECG Analysis System
Regulation	21 CFR 870.2340, 21 CFR 870.1425
Product Code	DPS;DQK
Reviewing Panel/Branch	Cardiovascular
Submission Number	K223013

5.6 Predicate Device(s)

Table - 5.1 Predicate Device(s)

Predicate Type	510(k) Number	Device Name	Manufacturer	Product Code
Primary	K212112	Cardiologs Holter Platform	Cardiologs Technologies	DPS,DQK

5.7 Device Description

The AccurECG Analysis System ("AccurECG" or the "System") consists of: (1) A client-side web interface which provides tools to upload and review ECG recordings via a web application programming interface (API), and (2) A server-side automated proprietary ECG interpretation support algorithm which measures and analyzes ECGs to provide physicians supportive information for ECG analysis.

AccurECG is intended to analyze recordings performed on adults over the age of 22 and works in the following sequence:

i. The web interface allows the user to select files and upload to the AccurECG secure database.
ii. The proprietary AccurECG algorithm analyzes and labels the ECG:
    - Delineation – detection of QRS complexes and T waves on the ECG signal through advanced signal processing and image-based techniques.
    - Abnormality labels – automated arrhythmia interpretation and statistical classification.
iii. AccurECG Analysis System displays the resulting analysis and original ECG signal with reviewing tools in the web interface.
iv. AccurECG Analysis System allows for preliminary comments summarizing the review before generating a report.

5.8 Intended Use/Indications for Use

The AccurECG Analysis System is intended for use by qualified healthcare professionals in the assessment of a patient's recorded ambulatory ECG data. Analysis results are provided in a standard report for review and printing.

The System provides single-lead analysis on a beat-by-beat basis, Ventricular Ectopic Beat and Supraventricular Ectopic Beat detection, heart rate measurement, and rhythm analysis. The AccurECG Analysis System is compatible with ECG recordings taken with silver/silver chloride (Ag / AgCl) electrodes (wet leads).

The AccurECG Analysis System is not for use in life-supporting or sustaining systems or ECG monitor and alarm devices. The System is not intended to be used with cardiac telemetry monitors.

The AccurECG Analysis System's automated interpretation results are not intended to be the sole means of diagnosis. The AccurECG Report is an adjunct intended to facilitate health care decision making in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information to arrive at a diagnostic conclusion.

The AccurECG Analysis System does not interface with data management systems or hardware and is device independent.

5.9 Comparison of Technological Characteristics with Predicate

The subject device has the same intended use and substantially equivalent technological characteristics that do not raise questions of safety or effectiveness. Table - 5.2 Feature Comparison: AccurECG System to the predicate device illustrates a comparison of detection features between the AccurECG system and the cited predicate.

Table - 5.2 Feature Comparison: AccurECG to the predicate device

Feature	AccurECG	CardioLogs ECG Analysis Platform
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 - 5.3 Comparison of technological characteristics: AccurECG to the predicate device provides a comparison of the technological characteristics of the AccurECG System with the cited predicate.

Table - 5.3 Comparison of technological characteristics: AccurECG System to the predicate device

	AccurECG (this submission)	CardioLogs ECG Analysis Platform (K170568)	Comparison to predicate device
Device Trade Name	AccurECG® Analysis System	CardioLogs ECG Analysis Platform	N/A
Manufacturer	AccurKardia, Inc.	CardioLogs Technologies	N/A
510(K) No.	(this submission)	K212112	N/A
Regulation Number	21 CFR 870.2340 21 CFR 870.1425	21 CFR 870.2340 21 CFR 870.1425	Same
Product Code	DQK, DPS	DQK, DPS	Same
Class	2	2	Same
Device Class/Name	Electrocardiograph	Electrocardiograph	Same
Software Level of Concern	Major	Moderate	Same

Indications for Use	The AccurECG Analysis System is intended for use by qualified healthcare professionals ("HCP") in the assessment of a patient's recorded ambulatory ECG data. Analysis results are provided in a standard report for review and printing. The System provides single-lead analysis on a beat-by-beat basis, Ventricular Ectopic Beat and Supraventricular Ectopic Beat detection, heart rate measurement, and rhythm analysis. The AccurECG Analysis System is compatible with ECG recordings taken with silver/silver chloride (Ag / AgCl) electrodes (wet leads). The AccurECG Analysis System is not for use in life-supporting or sustaining systems or ECG monitor and alarm devices. The System is not intended to be used with cardiac telemetry monitors. The AccurECG Analysis System's automated interpretation results are not intended to be the sole means of diagnosis. The AccurECG Report is an adjunct intended to facilitate health care decision making in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information to arrive at a diagnostic conclusion. The AccurECG Analysis System does not interface with data management systems or hardware and is device independent.	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. 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.	The predicate device is indicated for pediatric as well as adult patients.

Fundamental scientific technology	The AccurECG Analysis System consists of: An interface which provides tools to upload, analyze, review ECG data coded in Java. An automated proprietary ECG interpretation support algorithm which measures and analyses ECGs to provide supportive information for ECG diagnosis, written in LabVIEW using the G Programming language. This application is accessed through an Internet connection and a web browser connected to the AccurECG Application Programming Interface (API).	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 AccurECG Analysis System does not present any major technological differences compared to the predicate device. Substantially equivalent: Both devices provide a web interface which provides tools to upload, analyze, review ECG data, but are coded in a different programming language, which should not have any effect on intended use or performance and does not introduce new issues of safety or effectiveness. Both are accessed through an internet connection and a web browser, but the predicate device can also be accessed through a direct connection to the API. This connection difference should not have any effect on intended use or performance and does not introduce new issues of safety or effectiveness.

5.10 Summary of Performance Data

Performance tests have been conducted in conformance with the following FDA-recognized consensus standards.

- AAMI/ANSI EC 57:2012 Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
- IEC 60601-2-47:2012 Medical Electrical Equipment, Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems (Section 201.12.1.101 - Algorithm Testing).

5.11 Software verification and validation

Testing described in this premarket notification consisted of verification of all design input requirements and product specifications. All clinical input requirements were validated against a gold standard. There are 2 residual anomalies appeared during verification and software validation tests. The details of the Anomalies can be found in the APPX 44 PRJ-21-059 v05 Software Anomalies Listing, AccurECG.
Usability of the AccurECG Analysis System was tested throughout development, validating the effectiveness of risk control measures associated with the user interface. AccurKardia conducted usability tests of the AccurECG user interface with Certified Cardiovascular Technicians to evaluate the effectiveness of the design, labeling and risk. The protocols cover the testable technical requirements relevant to the user interface as described in the User Interface Specification.

5.12 Conclusion

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