December 22, 2025

AccurKardia Inc.
% Kwame Ulmer
Regulatory Consultant, Official Correspondent
MedTech Impact Partners
16844 Margate Street
Encino, California 91436

Re: K252361
Trade/Device Name: AccurECG Analysis System (v2.0)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK
Dated: November 26, 2025
Received: November 26, 2025

Dear Kwame Ulmer:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

KIMBERLY N. CROWLEY -S

Digitally signed by KIMBERLY N. CROWLEY -S

For: Jennifer 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252361

Device Name

AccurECG Analysis System (v2.0)

Indications for Use *(Describe)*

The AccurECG® Analysis System v2.0 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 v2.0 is compatible with ECG recordings taken with silver/silver chloride (Ag / AgCl) electrodes (wet leads).

The AccurECG® Analysis System v2.0 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 v2.0 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.

101 Avenue of Americas,
Suite 931,
New York, NY 10013

510(k) Summary

1. General Information

1.1. Applicant/Submitter

AccurKardia, Inc.
101 Avenue of the Americas
Suite 931
New York, NY 10013
Phone Number: +1-718-708-3522
Website: www.accurkardia.com

Contact Person: Juan Jiménez
Phone: +1 (718) 708-3522
Email: jcj@accurkardia.com

1.2. Correspondent Information

Official Correspondent: Kwame Ulmer
Correspondent Phone: +1 (202) 596-2492
Correspondent Email: kwame.ulmer@medtechimpactpartners.com

1.3. Date of Preparation

November 26, 2025

2. Device Information

2.1. Subject Device

Device Name	AccurECG® Analysis System v2.0
Model Number	v2.0
Regulation Name	Electrocardiograph
Regulation	21 CFR 870.2340
Product Code	DPS, DQK
Regulatory Panel	Cardiovascular
Submission Number	K252361

2.2. Predicate Device

Device Name	AccurECG® Analysis System
Model Number	v1.3.0
Regulation Name	Electrocardiograph
Regulation	21 CFR 870.2340
Product Code	DPS, DQK
Regulatory Panel	Cardiovascular
Submission Number	K223013

3. Device Description

The AccurKardia ECG Analysis 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 v2.0 is intended to analyze recordings performed on adults aged 22 and older 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 v2.0 displays the resulting analysis and original ECG signal with reviewing tools in the web interface.

iv. AccurECG® Analysis System v2.0 allows for preliminary comments summarizing the review before generating a report.

4. Intended Use / Indications for Use

The AccurECG® Analysis System v2.0 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 v2.0 is compatible with ECG recordings taken with silver/silver chloride (Ag / AgCl) electrodes (wet leads).

The AccurECG® Analysis System v2.0 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 v2.0 does not interface with data management systems or hardware and is device independent.

5. Comparison of Technological Characteristics with Predicate

The software features have been modified in comparison to the predicate device to support enhanced device functionality. The modifications include changes to the operating system and programming language; however, the intended use, indications for use, technological characteristics, usability, and principles of operation of the subject device remain identical to those of the predicate device cleared under Premarket Notification K223013. The following table (**Table 1**) demonstrates the substantial equivalence comparison between the subject and predicate device.

There is no impact on the substantial equivalence of the AccurECG® Analysis System v2.0. Based on these considerations, the subject device is considered substantially equivalent to the predicate device in accordance with FDA Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (Jul. 28, 2014).

Table 1 – Substantial Equivalence Table

Technological Characteristics	PREDICATE DEVICE **AccurECG® Analysis System (K223013)**	SUBJECT DEVICE **AccurECG® Analysis System v2.0**	COMPARISON
Manufacturer	AccurKardia Inc.	AccurKardia Inc	Same
510(k)	K223013	K252361	Same
Classification Regulation	21 CFR 870.2340 21 CFR 870.1425	21 CFR 870.2340 21 CFR 870.1425	Same
Product Codes	DPS, DQK	DPS, DQK	Same
Regulatory Class	II	II	Same
Classification Name	Electrocardiograph	Electrocardiograph	Same
Indications for Use	The AccurECG® Analysis System is intended for use by qualified	The AccurECG® Analysis System v2.0 is intended for use by	Same

Technological Characteristics	PREDICATE DEVICE **AccurECG® Analysis System (K223013)**	SUBJECT DEVICE **AccurECG® Analysis System v2.0**	COMPARISON
	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	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 v2.0 is compatible with ECG recordings taken with silver/silver chloride (Ag / AgCl) electrodes (wet leads). The AccurECG® Analysis System v2.0 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 v2.0'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	

Technological Characteristics	PREDICATE DEVICE **AccurECG® Analysis System (K223013)**	SUBJECT DEVICE **AccurECG® Analysis System v2.0**	COMPARISON
	arrive at a diagnostic conclusion. The AccurECG® Analysis System does not interface with data management systems or hardware and is device independent.	diagnostic information to arrive at a diagnostic conclusion. The AccurECG® Analysis System v2.0 does not interface with data management systems or hardware and is device independent.	
Device Description	The AccurKardia ECG Analysis 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	The AccurKardia ECG Analysis System v2.0 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 v2.0 is intended to analyze recordings performed on adults aged 22 and older 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	Same

Technological Characteristics	PREDICATE DEVICE **AccurECG® Analysis System (K223013)**	SUBJECT DEVICE **AccurECG® Analysis System v2.0**	COMPARISON
	waves on the ECG signal through advanced signal processing and image-based techniques. ○ Abnormality labels – automated arrhythmia interpretation and statistical classification. iii. The AccurECG® Analysis System displays the resulting analysis and original ECG signal with reviewing tools in the web interface. iv. The AccurECG® Analysis System allows for preliminary comments summarizing the review before generating a report.	waves on the ECG signal through advanced signal processing and image-based techniques. ○ Abnormality labels – automated arrhythmia interpretation and statistical classification. iii. The AccurECG® Analysis System v2.0 displays the resulting analysis and original ECG signal with reviewing tools in the web interface. iv. The AccurECG® Analysis System v2.0 allows for preliminary comments summarizing the review before generating a report.	
Patient Population	Adults aged 22 and older Prescribed for out-patient cardiac monitoring for up to ten days	Adults aged 22 and older Prescribed for out-patient cardiac monitoring for up to ten days	Same
Use Environment	Office or clinical setting at a workstation equipped with a PC and high-speed internet access	Office or clinical setting at a workstation equipped with a PC and high-speed internet access	Same
Intended User	Qualified healthcare professionals (including ECG technicians, medical supervisors (MDs), and healthcare providers)	Qualified healthcare professionals (including ECG technicians, medical supervisors (MDs), and healthcare providers)	Same
Electrocardiograph Signal Requirements			
ECG File Format	.DAT, .HEA, .ECG (ISHINE-formatted Holter ECG file) or .EDF format from single lead ambulatory ECG device	.DAT, .HEA, .ECG (ISHINE-formatted Holter ECG file) or .EDF format from single lead ambulatory ECG device	Same

Technological Characteristics	PREDICATE DEVICE **AccurECG® Analysis System (K223013)**	SUBJECT DEVICE **AccurECG® Analysis System v2.0**	COMPARISON
Duration	10 - 32.9 seconds	10 - 32.9 seconds	Same
Sampling frequency	200 Hz – 1000 Hz	200 Hz – 1000 Hz	Same
Resolution	11Bit and 16 Bit	11Bit and 16 Bit	Same
Lead positioning	Lead II	Lead II	Same
Supported electrode types	Wet Silver (Ag) / Silver Chloride (AgCl) ECG electrodes with conductive gel	Wet Silver (Ag) / Silver Chloride (AgCl) ECG electrodes with conductive gel	Same
AccurECG System Requirements			
Device Execution Environment (Cloud-Based)	Windows Virtual Machines	Ubuntu Linux Virtual Machines	Substantially Equivalent: ISO 14971 risk analysis and verification / validation testing have confirmed differences do not introduce new questions of safety and effectiveness. Device inputs/outputs and user interface remain the same between both the subject and the predicate device.
Programming Language	LabVIEW (G Programming Language)	Python	Substantially Equivalent: The different programming language does not impact the core functionality, principles of operation, or performance of the device. ISO 14971 risk analysis and verification / validation testing have confirmed differences do not introduce new

Technological Characteristics	PREDICATE DEVICE **AccurECG® Analysis System (K223013)**	SUBJECT DEVICE **AccurECG® Analysis System v2.0**	COMPARISON
			questions of safety and effectiveness. Device inputs/outputs and user interface remain the same between both the subject and the predicate device.
End-User System Requirements for Viewing			
End-user Compatible Workstation PC	Microsoft® Windows® 10 version 21H2 or later	Microsoft® Windows® 11 Version 24H2 for x64-based Systems (KB5055523) as the minimum desktop OS	Same - Both configurations specify currently supported Microsoft Windows operating systems consistent with vendor-supported release versions
Display Resolution	1920 X 1080 (1080p Monitor recommended)	1920 X 1080 (1080p Monitor recommended)	Same
Web Browser	Google Chrome Web Browser (Version 81.0 or later)	Google Chrome Web Browser (Version 134.0 or later)	Same
Pdf Report Viewer	Adobe Acrobat Reader DC (2020.012 or later) with Adobe Acrobat Extension for Chrome (Version 17 or later), or Adobe Acrobat Pro DC (2020.012 or later) with Adobe Acrobat Extension for Chrome (Version 15 or later)	Adobe Acrobat Reader DC (25.001.20458 or later) with Adobe Acrobat Extension for Chrome (Version 17 or later), or Adobe Acrobat Pro DC (25.001.20458 or later) with Adobe Acrobat Extension for Chrome (Version 15 or later)	Same
Device Outputs			
Heart rate determination (non-paced adult)	Yes	Yes	Same
QRS Detection	Yes	Yes	Same

Technological Characteristics	PREDICATE DEVICE **AccurECG® Analysis System (K223013)**	SUBJECT DEVICE **AccurECG® Analysis System v2.0**	COMPARISON
Non-paced arrhythmia interpretation	Yes	Yes	Same
Non-paced ventricular arrhythmia calls	Yes	Yes	Same
Intervals measurements	Yes	Yes	Same
Ventricular ectopic beat detection	Yes	Yes	Same

6. Summary of Performance Data

A summary of the performance data, which was based upon well-established test methods and FDA-recognized consensus standards, demonstrate conformity to the intended use. Performance testing applicable to the subject device was completed to ensure it performs as intended per the product specifications and requirements. The following testing has been completed in support of the AccurECG® Analysis System v2.0, and all acceptance criteria were met:

- Unit testing
- Code review
- Software module verification testing
- Field level verification testing
- System verification testing
- Performance evaluation
- Cybersecurity testing

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)

Comparative performance testing demonstrated statistical equivalence between the subject device and the predicate device. For every measured parameter, the 95% confidence interval lay within the

specified equivalence margin. These results support that no new questions of safety or effectiveness are raised, and the subject device is considered substantially equivalent to the predicate device based on the performance data collected.

7. Conclusion

Based upon the Intended Use, Indications for Use, product technical information, performance testing and evaluation, and standards compliance provided in this premarket notification, the AccurECG® Analysis System v2.0 has been shown to be substantially equivalent to the cited predicate.