



March 11, 2019

AliveCor, Inc.
Prabhu Raghavan
Vice President of Regulatory and Quality
444 Castro Street, Suite 600
Mountain View, California 94041

Re: K181823
Trade/Device Name: KardiaAI
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: February 8, 2019
Received: February 11, 2019

Dear Prabhu Raghavan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 **Jessica E. Paulsen -S**
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181823

Device Name

KardiaAI

Indications for Use (Describe)

The KardiaAI is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects. The device supports analyzing data recorded in compatible formats from any ambulatory ECG devices such as event recorders, or other similar devices. The library is intended to be integrated into other device software. The library is not intended for use in life supporting, or sustaining systems, or ECG monitors, or cardiac alarm, or OTC use only devices.

The KardiaAI library provides the following capabilities:

- ECG noise filtering,
- heart rate measurement from ECGs,
- detection of noisy ECGs, and
- ECG rhythm analysis for detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia (when prescribed or used under the care of a physician).

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.

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510(k) Notification K181823

GENERAL INFORMATION [807.92(a)(1)]

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Date Prepared: March 06, 2019

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

KardiaAI

Generic/Common Name:

Programmable diagnostic computer

Classification:

21 CFR§870.1425, Programmable diagnostic computer, Class II

Product Code:

DQK, DPS

PREDICATE DEVICE(S) [807.92(a)(3)]

- Primary predicate: AliveCor, Inc., Kardia Band System, K171816
- Secondary predicate: CardioLogs Technologies, CardioLogs ECG Analysis Platform, K170568

DEVICE DESCRIPTION [807.92(a)(4)]

KardiaAI is a software library that implements various ECG processing and analysis algorithms. This Software as a Medical Device (SaMD) computes various physiologic parameters from a 30-second ECG and provides these capabilities in the form of an Application Program Interface (API) library. ECG devices can incorporate the API library into ECG device (“target device”) software to enable algorithmic analysis of ECGs to provide analytical capabilities. The device provides ECG noise filtering and detection of noisy ECGs as well as identifies normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia.

INDICATIONS FOR USE [807.92(a)(5)]

KardiaAI is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects. The device supports analyzing data recorded in compatible formats from any ambulatory ECG devices such as event recorders, or other similar devices. The library is intended to be integrated into other device software. The library is not intended for use in life supporting, or sustaining systems, or ECG monitors, or cardiac alarm, or OTC use only devices.

The KardiaAI provides the following capabilities:

- ECG noise filtering,
- heart rate measurement from ECGs,
- detection of noisy ECGs, and
- ECG rhythm analysis for detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia (when prescribed or used under the care of a physician).

SUBSTANTIAL EQUIVALENCE

KardiaAI has the same intended use as the predicate devices for the purpose of analyzing ambulatory ECG recordings. All three devices analyze ECGs for non-active patient monitoring or non-urgent clinical decision making. KardiaAI and the predicate devices all condition and analyze ECG signals from ambulatory Lead I ECG devices and provide data for display on the ECG target devices. KardiaAI shares the atrial fibrillation (AF), normal sinus rhythm (NSR), and noise algorithm with the Kardia Band System predicate device and contains the additional classifiers for bradycardia and tachycardia. Further, like the CardioLogs predicate device, KardiaAI is a SaMD with API for connecting with ECG devices and sending algorithm output for display. As such, the device has the same intended use as the predicate devices and similar technological characteristics.

Differences between the subject device and the predicates have been tested to ensure that the device meets its intended use. Therefore, KardiaAI is substantially equivalent to the predicate devices.

Comparison of Technological Characteristics with the Predicate Devices

Feature	AliveCor KardiaAI	AliveCor Kardia Band System (K171816)	CardioLogs Technologies CardioLogs ECG Analysis Platform (K170568)
Product Code	DQK, Computer, Diagnostic, Programmable DPS, Electrocardiograph	DPS, Electrocardiograph DXH, Transmitters And Receivers, Electrocardiograph, Telephone	DQK, Computer, Diagnostic, Programmable DPS, Electrocardiograph
Regulation	870.1425, Programmable diagnostic computer	870.2920, Telephone electrocardiograph transmitter and receiver	870.1425, Programmable diagnostic computer
Indications for use	<p>KardiaAI is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects.</p> <p>The device supports analyzing data recorded in compatible formats from any ambulatory ECG devices such as event recorders, or other similar devices. The library is intended to be integrated into other device software.</p> <p>The library is not intended for use in life supporting, or sustaining systems, or ECG monitors, or cardiac alarm, or OTC use only devices.</p> <p>KardiaAI provides the following capabilities:</p> <ul style="list-style-type: none"> ● ECG noise filtering, ● heart rate measurement from ECGs, ● detection of noisy ECGs, and ● ECG rhythm analysis for detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia 	<p>The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms.</p> <p>The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician).</p> <p>The Kardia Band System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.</p>	<p>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.</p> <p>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.</p> <p>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.</p>

510(k) SUMMARY

Feature	AliveCor KardiaAI	AliveCor Kardia Band System (K171816)	CardioLogs Technologies CardioLogs ECG Analysis Platform (K170568)
	(when prescribed or used under the care of a physician).		<p>The CardioLogs ECG Analysis Platform is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices.</p> <p>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.</p> <p>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.</p>
Target population	Adults (over 18)	Adults (over 18)	Adults (over 18)
Components	Software only	Software and ECG recording device	Software only

510(k) SUMMARY

Feature	AliveCor KardiaAI	AliveCor Kardia Band System (K171816)	CardioLogs Technologies CardioLogs ECG Analysis Platform (K170568)
Software Functional Comparisons	<ul style="list-style-type: none"> - An interface that provides tools to process and analyze ECGs through various algorithms - The automated proprietary ECG algorithms provide supportive information for ECG diagnosis. The library can be accessed by directly connecting to the KardiaAI's Application Programming Interface 	<ul style="list-style-type: none"> - Kardia watch app software used to analyze and display ECG signals received from the Kardia Band hardware - Kardia phone app used to create Kardia account, onboard users, store, re-display and transfer ECGs received from the Kardia watch app 	<ul style="list-style-type: none"> - 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, <p>This application can be accessed through an Internet connection and a web browser, or is directly connected to the CardioLogs' Application Programming Interface (API)</p>

PERFORMANCE DATA [807.92(b)]

All necessary testing was conducted on the KardiaAI to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary [807.92(b)(1)]

Non-clinical testing was conducted to assess algorithm performance and to verify that KardiaAI performs as intended. Algorithm performance testing was assessed using ECG databases from the ANSI/AAMI EC57:2012 standard as well as AliveCor proprietary databases. The overlapping algorithms between KardiaAI and the Kardia Band System met the same performance acceptance criteria. The results of the testing demonstrate that KardiaAI performs to its specifications and meets its intended use, which is substantially equivalent to that of the predicate devices.

CONCLUSIONS [807.92(b)(3)]

The results of nonclinical testing demonstrate that the KardiaAI meets its intended use which is equivalent to that of the predicate devices. The overlapping AF, NSR, and noise algorithms for KardiaAI and Kardia Band System met the same performance acceptance criteria. Testing also ensured that differences in technological characteristics between the KardiaAI and the Kardia Band System (primary predicate) (i.e., bradycardia and tachycardia algorithms as well as multi-lead ambulatory ECG input) perform as intended and do not raise different questions of safety or effectiveness.