November 12, 2020

AliveCor, Inc.
% Prabhu Raghavan
Principal
MDQR, LLC
444 Castro Street, Suite 600
Mountain View, California 94041

Re: K201985
Trade/Device Name: KardiaAI
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: October 12, 2020
Received: October 13, 2020

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/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,

Jennifer Shih
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201985

Device Name

KardiaAI

Indications for Use *(Describe)*

KardiaAI is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects (when prescribed or used under the care of a physician). 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:
- Filtering ECG noise,
- Reporting heart rate measurement from ECGs,
- Detecting noisy ECGs,
- Reporting ECG rhythm analysis for the presence of sinus rhythm, atrial fibrillation, bradycardia, and tachycardia; for ECGs detected as sinus rhythm, detecting normal sinus rhythm, sinus rhythm with wide QRS, sinus rhythm with premature ventricular contractions (PVC), and sinus rhythm with supraventricular ectopy,
- Detecting QRS complexes in an ECG,
- For ECGs detected as sinus rhythm, classifying individual beats as a PVC or non-PVC beat, and
- Generating an average beat from an ECG

The device is not intended for use in patients who have pacemakers, ICDs, or other implanted electronic devices.

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) Summary for K201985

Prepared in accordance with the requirements of 21 CFR 807.92

Submitter Information [807.92(a)(1)]

Submitter/Applicant	AliveCor, Inc. 444 Castro Street, Suite 600 Mountain View, CA 94041 Phone: 650-396-8553 Fax: 650-282-7932
Primary Contact Person	Prabhu Raghavan Regulatory Consultant for AliveCor MDQR, LLC 444 Castro Street, Suite 600 Mountain View, CA 94041 Phone: 408-316-5707 Fax: 650-282-7932 Email: prabhu@mdqr.solutions
Submitter and Secondary Contact Person	Saket Bhatt VP of Regulatory and Quality 444 Castro Street, Suite 600 Mountain View, CA 94041 Phone: 408-701-7319 Fax: 650-282-7932 Email: ra@alivecor.com
Date Prepared	July 15, 2020

Device Information [807.92(a)(2)]

Trade Name	KardiaAI
Common Name	Programmable diagnostic computer
Classification	21 CFR§870.1425
Device Class	Class II
Product Code	DQK
Subsequent Product Code	DPS

Predicate Information [807.92(a)(3)]

Predicate(s)	AliveCor, Inc., KardiaAI, K181823

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 an ECG and provides these capabilities in the form of an Application Program Interface (API)

library. AliveCor-designed ECG devices ("target device") incorporate the API library into their device software to enable algorithmic analysis of ECGs to provide analytical capabilities. KardiaAI provides ECG processing functions, including ECG noise filtering and detection of noisy ECGs. It performs rhythm analysis on ECGs, specifically detecting atrial fibrillation, bradycardia, tachycardia and sinus rhythm, which can be further classified as normal sinus rhythm, sinus rhythm with wide QRS, sinus rhythm with premature ventricular contractions (PVCs), and sinus rhythm with supraventricular ectopy. It further provides beat-level annotations, including beat-level QRS locations, and, for sinus rhythm ECGs, PVC/not-PVC annotations. It also provides an average beat ECG representation, and the R-R interval tachogram. Recording and viewing of ECGs and the results of the KardiaAI analyses are to be provided by other AliveCor FDA-cleared devices (i.e., the target devices) into which the API library is incorporated, such as AliveCor's Triangle System (K183319) and KardiaMobile System (K182396).

Indications for use [807.92(a)(5)]
KardiaAI is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects (when prescribed or used under the care of a physician). 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:

- Filtering ECG noise,
- Reporting heart rate measurement from ECGs,
- Detecting noisy ECGs,
- Reporting ECG rhythm analysis for the presence of sinus rhythm, atrial fibrillation, bradycardia, and tachycardia; for ECGs detected as sinus rhythm, detecting normal sinus rhythm, sinus rhythm with wide QRS, sinus rhythm with premature ventricular contractions (PVC), and sinus rhythm with supraventricular ectopy,
- Detecting QRS complexes in an ECG,
- For ECGs detected as sinus rhythm, classifying individual beats as a PVC or non-PVC beat, and
- Generating an average beat from an ECG

The device is not intended for use in patients who have pacemakers, ICDs, or other implanted electronic devices.

Substantial Equivalence
The subject device has the same intended use as the predicate device. Both devices intended are to process (e.g., filter and detect noise) and analyze a single channel ECG signal to detect the presence of arrhythmias. These ECG analysis outputs from the subject and predicate device all represent potential findings to be reviewed and interpreted by a qualified healthcare professional, and do not represent complete diagnoses. Both devices are software-only API libraries and are intended to be incorporated into other AliveCor-designed medical devices ("target device"). Both the subject and predicate device process and analyze recorded ECGs, the output of which are stored, transferred, and displayed by the target device.

The subject device includes all the software outputs of the predicate device with updates in algorithm design and provides several new analysis outputs which are within the general intended use shared with the predicate device. Like the predicate device, the subject device's ECG analysis functionalities with respect to arrhythmia detection are prescription features.

As such, the subject device has the same intended use and technological characteristics as the predicate device. Differences between the subject device and the predicate device do not raise different questions of safety or effectiveness from the predicate device, and performance testing has demonstrated that the subject device meets its performance specifications and is as safe and as effective as the predicate device for their intended use. Therefore, KardiaAI is substantially equivalent to the predicate device.

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	**AliveCor KardiaAI (Subject Device)**	**AliveCor KardiaAI (K181823) (Predicate Device)**
Product Code	DQK, Computer, Diagnostic, Programmable DPS, Electrocardiograph	DQK, Computer, Diagnostic, Programmable DPS, Electrocardiograph
Regulation	21 CFR§870.1425, Programmable diagnostic computer Class II	21 CFR§870.1425, Programmable diagnostic computer Class II

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	**AliveCor KardiaAI (Subject Device)**	**AliveCor KardiaAI (K181823) (Predicate Device)**
Indications for use	KardiaAI is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects (when prescribed or used under the care of a physician). 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: ● Filtering ECG noise, ● Reporting heart rate measurement from ECGs, ● Detecting noisy ECGs, ● Reporting ECG rhythm analysis for the presence of sinus rhythm, atrial fibrillation, bradycardia, and tachycardia; for ECGs detected as sinus rhythm, detecting normal sinus rhythm, sinus rhythm with wide QRS, sinus rhythm with premature ventricular contractions (PVC), and sinus rhythm with supraventricular ectopy, ● Detecting QRS complexes in an ECG, ● For ECGs detected as sinus rhythm, classifying individual beats as a PVC or non-PVC beat, and ● Generating an average beat from an ECG The device is not intended for use in patients who have pacemakers, ICDs, or other implanted electronic devices	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. 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).
Target population	Adults (over 18)	Adults (over 18)
Components	Software only	Software only

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	**AliveCor KardiaAI (Subject Device)**	**AliveCor KardiaAI (K181823) (Predicate Device)**
Software Functionalities	• 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	• 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
Compatible ECG Devices	• Triangle System (K183319) • KardiaMobile System (K182396) • Omron Model BP7900 Blood Pressure Monitor + EKG (K182579)	• Triangle System (K183319) • KardiaMobile System (K182396) • KardiaBand System (K171816) • Omron Model BP7900 Blood Pressure Monitor + EKG (K182579)

Performance Data [807.92(b)]
All necessary testing was conducted on KardiaAI to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary [807.92(b)(1)]
Nonclinical testing, similar to that conducted to support the predicate device, was conducted to assess algorithm performance and to verify that KardiaAI performs as intended.

Software testing was conducted for KardiaAI. Specifically, algorithm performance testing was assessed using an AliveCor proprietary ECG database. Additional comparative testing was also performed on databases from the ANSI/AAMI EC57. All analysis outputs were found to meet their performance specifications. Specifically, for the algorithm outputs which are present in both KardiaAI and the predicate device, comparative testing was conducted, and it was found that the subject device demonstrated equivalent performance to the predicate device. 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 device.

In addition, a human factors usability study was conducted in accordance with recommendations in IEC 62366-1:2015, "*Medical devices - Part 1: Application of usability engineering to medical devices*", and FDA Guidance, "*Applying Human Factors and Usability Engineering to Medical Devices*", issued February 3, 2016. The results of the study demonstrated that users can use the device and understands its outputs based on labeling, and further understand appropriate actions if symptoms are present, such as when to seek medical care.

Conclusions [807.92(b)(3)]

KardiaAI has the same intended use as the predicate device, and any differences in technological characteristics do not raise different questions of safety or effectiveness. Differences between the subject device and the predicate device have been tested to ensure that the device meets its intended use. The results of nonclinical testing specifically demonstrate that KardiaAI meets its intended use which is equivalent to that of the predicate device. Therefore, KardiaAI is substantially equivalent to the predicate device.