January 24, 2020

AliveCor, Inc.
Saket Bhatt
Senior Manager, Regulatory Affairs
444 Castro Street, Suite 600
Mountain View, California 94041

Re: K191406
Trade/Device Name: KardiaMobile, KardiaStation
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone electrocardiograph transmitter and receiver
Regulatory Class: Class II
Product Code: DXH, DPS, QDA
Dated: December 20, 2019
Received: December 23, 2019

Dear Saket Bhatt:

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,

Hetal Patel
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)*
K191406

Device Name
KardiaMobile System

Indications for Use *(Describe)*
The KardiaMobile System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The KardiaMobile System also displays ECG rhythms and output of ECG analysis from AliveCor's KardiaAI platform including detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, and others. The KardiaMobile System is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and is not intended for pediatric use.

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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"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) Notification K191406

GENERAL INFORMATION [807.92(a)(1)]

Applicant:
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Date Prepared: January 22, 2020

DEVICE INFORMATION [807.92(a)(2)]

Trade/Proprietary Name:
KardiaMobile System

Generic/Common Name:
Telephone electrocardiograph transmitter and receiver

Classification:
21 CFR§870.2920, Telephone electrocardiograph transmitter and receiver, Class II

Product Code:
DXH, DPS, QDA

Establishment Registration:
3009715978

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

K182396 – AliveCor KardiaMobile System (Primary predicate)
DEN180044 – Apple Inc. ECG App (Secondary predicate)

DEVICE DESCRIPTION [807.92(a)(4)]

The KardiaMobile System is a trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorder that records, stores and transfers single-channel electrocardiogram rhythms. The device utilizes the computing power of Apple iOS- and Google Android-based smartphones to obtain and analyze single-channel ECG. These smartphones are termed Mobile Computing Platforms (MCPs). The device consists of the hardware (that has the electrodes), and the Kardia phone app (installed on an MCP). The same software is implemented in the iOS and Android MCP. In either configuration, the same hardware is used to sense the ECG. The KardiaMobile Hardware transmits the ECG signal from the electrode to the Kardia phone app on the MCP to be analyzed and presented to the user. All ECGs are synced with the user's account.

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

Indications for Use:

The KardiaMobile System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The KardiaMobile System also displays ECG rhythms and output of ECG analysis from AliveCor's KardiaAI platform including detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, and others. The KardiaMobile System is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and is not intended for pediatric use.

Type of Use:

Over-The-Counter Use (21 CFR 801 Subpart C)

Comparison with Predicate Devices:

The proposed device and both predicate devices have the same intended use of recording, displaying, analyzing, storing, and transferring single-lead ECG rhythms in an ambulatory setting. As such, the proposed device and its predicates are substantially equivalent with respect to intended use.

The proposed device and primary predicate device have similar Indications for Use which fall within the scope of the same intended use. The Indications for Use between the proposed device and primary predicate device (K182396) are highly similar and vary solely with respect to removal of the requirement for use under supervision of a clinician. The proposed device and secondary predicate device's (DEN180044) Indications for Use statements describe the same range of functionality with respect to ECG recording, display, and analysis; and neither device includes an unlock mechanism for access to any functionality or requires use "under the care of the physician," as is the case with the primary predicate device.

The KardiaMobile System has undergone evaluation in accordance to the Special Controls associated with 21CFR§ 870.2345, Electrocardiograph Software for Over-the-Counter Use. Specifically, human factors usability testing was conducted, where lay users have demonstrated the ability to both correctly use the device and understand the output of the device as designed when relying on only labeling. The evidence with the study results demonstrates that the removal of overread function brings the OTC use of the proposed device to be consistent with the secondary predicate device.

TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED WITH THE PREDICATE DEVICE [807.92(a)(6)]

The proposed KardiaMobile System device is highly similar to the primary predicate device with respect to technological characteristics, in terms of principle of operation, technological and performance characteristics (mechanism of action, environmental specifications, dimensional specifications, ergonomics of patient-user interface, packaging, sterilization and shelf life), materials, software and anatomical site. No modifications were made to the device hardware or to the Kardia app software's clinical functionalities with respect to ECG acquisition, display, and analysis as a result of this change.

The minor change which prompted this 510(k) is a change in the first-use onboarding procedure when the device is used in an OTC setting for new patients. While the predicate KardiaMobile System device required ECG review by a professional (i.e., "unlock overread") prior to a consumer patient gaining access to first-time ECG data analysis, the proposed KardiaMobile System device does not require the unlock overread. This onboarding step, without unlock overread, for the proposed KardiaMobile System device is similar to the secondary predicate device, the Apple Inc. ECG App (DEN180044), with respect to the lack of any unlocking requirements prior to access of ECG display and recording functions, therefore prompting its inclusion as a secondary predicate device. Specifically:

- With respect to the OTC Use Model, the primary predicate device's OTC use requires clinician overread, whereas the proposed device does not, in order to reduce the patient's burden of onboarding prior to use of the device and to improve AliveCor's operational efficiency. The removal of overread function does not add risk or remove mitigations of risk as compared with the primary predicate device as it only required a single time clinician interpretation of the patient's ECG, after which patients use the predicate device in the same manner as they would the proposed device. This updated OTC use case is further consistent with that of the ECG app secondary predicate device with respect to direct ECG display/analysis access without any "unlock" mechanisms.
- With respect to ECG recording and display, the ECG recording procedure of the proposed device is identical to that of the predicate devices, in which the user initiates contact with the electrodes of the device's hardware (the identical KardiaMobile hardware in the case of the proposed and primary predicate device, and consumer Apple Watch hardware in the case of the secondary predicate device), upon which ECG signal is recorded and processed by software. In all three (3) devices, the ECG recording is processed and displayed regardless of the ECG analysis outcomes, which allows the ECG signal to be evaluated independently by a trained physician (e.g., via sending an e-mailed PDF report). There are minor differences between the proposed and predicate devices with respect to the specific method of ECG display. In both the proposed and secondary

predicate devices, the ECG reading is displayed to the user via the associated software after the recording is complete. In the primary predicate device, the recording is similarly displayed for the user after recording completion under normal use, but for first-time use, the ECG recording is withheld from the user upon completion until the ECG signal recorded is reviewed by a board-certified cardiologist under the "overread unlock" mechanism.

- With respect to ECG analysis, after acquisition and initial processing of ECG signals, the proposed device and both predicate devices also include algorithms for filtering and analysis of ECG signals for arrhythmia. Specifically, all three (3) devices detect the presence of atrial fibrillation and Normal Sinus Rhythm. The proposed and primary predicate devices also detect the presence of two additional arrythmia conditions – bradycardia and tachycardia – which are within the shared intended use of the proposed and both predicate devices. All three (3) devices further provide outputs for non-determinative cases, i.e., in which the quality of the ECG may not enable the algorithmic determination, or in cases where the ECG may exhibit an arrhythmia other than those detectable by the algorithm. As such, the ECG algorithm outputs are similar between the proposed and predicate devices.

The removal of the unlock overread function does not introduce new risks or significantly modify existing risks, nor does it remove mitigations of risk as compared with the primary predicate device. The removal of overread function brings the OTC use of the product to be consistent with the secondary predicate device. Through human factors usability testing, it is demonstrated that users can use the device correctly solely based on labeling, and that the device labeling provides sufficient information to allow users to appropriately interpret the device output with respect to understanding the analysis output as well as when to seek medical attention.

Therefore, the proposed device and the predicate device share key technological characteristics, especially in reference to those associated with the key clinical functionalities of ECG recording, display, and analysis.

PERFORMANCE DATA [807.92(b)]

Performance testing of the proposed device was conducted in compliance to the special controls associated with Electrocardiograph Software for Over-the-Counter Use (Product Code: QDA), as demonstrated further within the table below. A further discussion of the testing conducted specifically to support the removal of "unlock overread" follows this Special Controls table.

Special Control	Summary of Conformance
1. Clinical performance testing under anticipated conditions of use must demonstrate the following: (a) The ability to obtain an ECG of sufficient quality for display and analysis; and	The KardiaMobile device has demonstrated its ability to obtain ECGs of sufficient quality for display and analysis through both bench and clinical performance testing.
(b) The performance characteristics of the detection algorithm as reported by sensitivity and either specificity or positive predictive value.	The KardiaMobile System leverages the KardiaAI SaMD (K181823) for ECG analysis. KardiaAI is validated in a dataset representative of the patient population of the proposed device. KardiaAI algorithm suite ECG detection algorithm outputs of Atrial Fibrillation, Normal, Bradycardia, Tachycardia, and Noise as well as the heart rate calculations were tested to meet the system requirements for sensitivity and specificity. Testing was conducted to ANSI/AAMI EC57:2012 databases and AliveCor's proprietary databases.
2. Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.	Software documentation for the KardiaMobile software was prepared and provided in accordance with FDA's Guidance titled, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2015).
3. Non-clinical performance testing must validate detection algorithm performance using a previously adjudicated data set	KardiaAI algorithm suite ECG detection algorithm outputs of Atrial Fibrillation, Normal, Bradycardia, Tachycardia, and Noise as well as the heart rate calculations were tested to meet the system requirements for sensitivity and specificity. Testing was conducted to ANSI/AAMI EC57:2012 databases and AliveCor's proprietary databases. These validation datasets are representative of the patient population of the proposed device.
4. Human factors and usability testing must demonstrate the following: (a) The user can correctly use the device based solely on reading the device labeling; and (b) The user can correctly interpret the device output and understand when to seek medical care.	Human factors evaluation was performed in accordance with recommendations in IEC62366-1:2015 and FDA's Guidance Document; *Applying Human Factors and Usability Engineering to Medical Devices:* • With respect to ECG acquisition, the proposed device uses the same hardware as the cleared KardiaMobile device (K182396 and prior clearances), which has a long history of real-world use. This real-world use data supports that representative users can record ECG of equivalent quality to 12-lead ECG. • With respect to ECG display and analysis, AliveCor has conducted an additional human factors usability study which specifically evaluated whether users can safely and effectively use the proposed device to view ECG signals and their analysis. The study found that the user can correctly use the device solely based on on-screen guidance and the users understand the device output. The study also found that users understand

Special Control	Summary of Conformance
	when to seek care regardless of the output of the device.
Labeling must include: (a) Hardware platform and operating system requirements (b) Situations in which the device may not operate at an expected performance level (c) A summary of the clinical performance testing conducted with the device;	Provided within applicable sections of the KardiaMobile Instructions for Use and User Manual documents.
(d) A description of what the device measures and outputs to the user; and (e) Guidance on interpretation of any results.	Provided within on-screen instructions to the user within the software, as well as applicable sections of the KardiaMobile Instructions for Use and User Manual documents.

Specifically to support the removal of "unlock overread," AliveCor has conducted software verification and validation testing in accordance to FDA's guidance titled, *General Principles of Software Validation* (January 11, 2002), which demonstrated that the minor software revisions to enable the change in the onboarding procedure is successfully implemented within the Kardia app. In addition, human factors usability testing was conducted to additionally confirm that representative users can use the device safely and effectively without supervision from a healthcare professional, and, furthermore, that the users understand when to seek medical help. This testing was performed in accordance with recommendations in FDA's Guidance Document titled, *Applying Human Factors and Usability Engineering to Medical Devices (*February 03, 2016), and IEC 62366-1:2015, *Medical devices - Part 1: Application of usability engineering to medical devices*.

The results of the collective testing demonstrated that the proposed KardiaMobile device is substantially equivalent to the predicate devices.

SUMMARY

AliveCor, Inc. considers the proposed KardiaMobile System device to be substantially equivalent to the legally marketed primary predicate KardiaMobile System (K182396) and the secondary predicate Apple Inc ECG App (DEN180044). Human factors usability testing, performed in agreement with recommendations in relevant FDA guidance documents and compliance standards, demonstrates that the removal of overread function brings the OTC use of the proposed device to be consistent with the secondary predicate device. The proposed KardiaMobile device is substantially equivalent to the predicate devices for its intended use.