May 25, 2022

AliveCor, Inc.
% Prabhu Raghavan
Principal Consultant
Mdqr, LLC.
189 N. Bernardo Ave. Suite 100
Mountain View, California 94043

Re: K220350
Trade/Device Name: KardiaMobile 6L
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH, DPS, QDA
Dated: February 24, 2022
Received: February 25, 2022

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 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)*
K220350

Device Name
KardiaMobile 6L

Indications for Use *(Describe)*
KardiaMobile 6L is intended to record, store and transfer one- and two-channel electrocardiogram (ECG) rhythms. In single channel mode, KardiaMobile 6L can record Lead-I. In two channel mode, KardiaMobile 6L can record Lead-I and Lead-II simultaneously and derive Lead-III and unipolar limb leads aVR, aVF and aVL. KardiaMobile 6L 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. KardiaMobile 6L 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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AliveCor®

510(k) Summary

Prepared in accordance with the requirements of 21 CFR 807.92

Submitter Information [807.92(a)(1)]

Submitter/Applicant	AliveCor, Inc. 189 N. Bernardo Ave. Suite 100 Mountain View, CA 94043 Phone: 650-396-8553 Fax: 650-282-7932
Primary Contact Person	Prabhu Raghavan Regulatory Consultant for AliveCor Principal Consultant, MDQR, LLC 189 N. Bernardo Ave. Suite 100 Mountain View, CA 94043 Phone: 408-316-5707 Fax: 650-282-7932 Email: prabhu@mdqr.solutions
Submitter and Secondary Contact Person	Susan Noriega VP of Regulatory Affairs, Clinical Affairs and Quality 189 N. Bernardo Ave. Suite 100 Mountain View, CA 94043 Phone: 650-793-1966 Fax: 650-282-7932 Email: snoriega630@alivecor.com
Date Prepared	February 02, 2022

Device Information [807.92(a)(2)]

Trade Name	KardiaMobile 6L
Common Name	Transmitters and Receivers, Electrocardiograph, Telephone,
Classification	21 CFR§870.2920
Device Class	Class II
Product Code	DXH
Subsequent Product Code	DPS, QDA

Predicate Information [807.92(a)(3)]

Predicate(s)	AliveCor, Inc., K210753, KardiaMobile 6L

Device Description [807.92(a)(4)]

KardiaMobile 6L is a trans-telephonic (transmission by smartphone) electrocardiogram (ECG) event recorder that records, stores, transfers, and analyzes single-channel or two channel ECG rhythm recordings. KardiaMobile 6L provides output of one or six ECG leads, including Lead I, Lead II, Lead III, aVL, aVR and aVF. The device utilizes the computing power of iOS-based or

Android-based devices (referred to as "Mobile Computing Platforms" (MCP) within this 510(k)) to record and analyze ECG signals. KardiaMobile 6L consists of KardiaMobile 6L Hardware (portable small wireless hardware with electrodes) and the Kardia Core app, which is installed on an MCP (i.e., iOS or Android devices). KardiaMobile 6L Hardware uses Bluetooth to transmit the ECG signal from the electrodes to the Kardia Core app on the MCP, which then displays the recorded ECG on the MCP's screen. The device is intended to be used by patients with known or suspected heart conditions and health conscious individuals as well as by healthcare professionals (HCPs) who want to remotely monitor their patient's heart health. The device is available for Over-the-Counter (OTC) as well prescription use. The Kardia Core app provides the complete ECG recording and analysis workflow, from acquisition of the signal from the KardiaMobile 6L hardware, to the display of the ECG and analysis results, to printing of the ECG rhythm strip. The app utilizes KardiaAI (K181823, K201985) to provide ECG analysis, which includes the determinations of Normal Sinus Rhythm, Atrial Fibrillation, Bradycardia, Tachycardia, or Unclassified to OTC users and additionally, Sinus Rhythm determinations (Sinus Rhythm with Wide QRS, Sinus Rhythm with Supraventricular Ectopy, and Sinus Rhythm with Premature Ventricular Contractions) for prescription-use only users.

The Kardia Core app may be distributed as is or be incorporated into other apps ("variants"), by AliveCor or by third-parties, that can provide additional functionality such patient/user onboarding, storage and review of past data, as well as providing secondary MDDS displays of other medical devices. The main software app variant, called the Kardia App, is the default software marketed with KardiaMobile 6L. Kardia App includes workflows for OTC user account creation, integration with AliveCor's KardiaPro MDDS portal, secondary display of Bluetooth-enabled blood pressure monitors, and other non-regulated or enforcement discretion features. Kardia App also provides workflows for patients to forward the recorded ECG to their HCP, who can review the ECG rhythm and measure the QT interval. An alternate software variant, called the KardiaStation App, incorporates the Kardia Core app to be used exclusively within hospitals and clinics by adding patient administration workflows. Finally, a third variant called Kardia Rx App incorporates the Kardia Core app to provide a simple workflow to transfer the data for remote patient monitoring applications.

Indications for use [807.92(a)(5)]
KardiaMobile 6L is intended to record, store and transfer one- and two-channel electrocardiogram (ECG) rhythms. In single channel mode, KardiaMobile 6L can record Lead-I. In two channel mode, KardiaMobile 6L can record Lead-I and Lead-II simultaneously and derive Lead-III and unipolar limb leads aVR, aVF and aVL. KardiaMobile 6L 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. KardiaMobile 6L 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.

Substantial Equivalence
The KardiaMobile 6L subject device has the same intended use, physical characteristics, and technological characteristics as the K210753, KardiaMobile 6L predicate device. The difference between the two devices is the reorganization of the software only and the addition of an

Application Program Interface for other apps to access Kardia Core workflows. Performance testing, utilizing test methods previously used in K183319 and K210753, were employed to ensure that the device meets its requirements and that the differences between the subject and predicate device do not raise different questions of safety or effectiveness.

Performance Data [807.92(b)]
All necessary testing was conducted on KardiaMobile 6L to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary [807.92(b)(1)]
Since both the subject and the predicate have the same hardware, verification activities focused on the changes related to the software reorganization. The subject device successfully passed the software verification test methods previously used in K183319 and K210753.

Clinical Testing Summary [807.92(b)(2)]
No clinical testing was required for the minor changes made to the software.

Conclusions [807.92(b)(3)]
The KardiaMobile 6L subject device has the same intended use as the predicate device, and the software changes to support the reorganization do not raise different questions of safety or effectiveness. The software changes between the subject device and the predicate device have been verified to ensure that the subject device is as safe and effective for its intended use as the predicate device. Therefore, the KardiaMobile 6L subject device is substantially equivalent to the predicate device.

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

Feature	**AliveCor KardiaMobile 6L (Subject Device)**	**AliveCor KardiaMobile 6L (K210753, Predicate Device)**
Product Code	DXH, DPS, QDA	No difference
Mechanism of Action	User completes circuit with skin contact and hardware transmits ECG signal to MCP to convert and display ECG waveform	No difference
Where used (intended use)	Mobile/active users at rest (ambulatory)	No difference
Use cases for HCPs	Rhythm analysis QT Interval Measurement	No difference
Anatomical sites	Left hand fingers to right hand fingers Left hand fingers to right hand fingers and to left leg/knee	No difference
Software application functions	• Medical device functions o Acquire ECG from KardiaMobile 6L Hardware	• Medical device functions o No difference

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

Feature	**AliveCor KardiaMobile 6L (Subject Device)**	**AliveCor KardiaMobile 6L (K210753, Predicate Device)**
	○ Record, transfer, and display an ECG, ○ ECG analysis of KardiaAI (K181823 or K201985), as applicable ○ Create a PDF rhythm strip of the recorded ECG ○ API for integrating with other mobile applications	• Provides additional nonmedical device or enforcement discretion functions such as workflows for user account creation, and onboarding, connecting to Bluetooth-enabled blood pressure monitors to provide a secondary display, share previously recorded ECG and blood pressure data with healthcare professionals, etc.
ECG Analysis Determinations using K181823 KardiaAI. In OTC and Rx Only type of use	Atrial Fibrillation Normal Sinus Rhythm Tachycardia Bradycardia Unclassified Unreadable	No difference
ECG Analysis Determinations using K201985 KardiaAI. In Rx Only type of use	Atrial Fibrillation Sinus Rhythm Sinus Rhythm with Wide QRS, Sinus Rhythm with Supraventricular Ectopy Sinus Rhythm with Premature Ventricular Contractions Normal Sinus Rhythm Tachycardia Bradycardia Unclassified Unreadable	No difference
Data Acquisition:		
Frequency Response	0.5Hz – 40Hz	No difference
No. of ECG electrodes	Three (3) dry electrodes	No difference
No. of ECG channels	Single-channel and two-channel	No difference
Resolution	16 bits	No difference
Sample Rate	300 Samples/Second	No difference
Power Supply:		
Battery	1 Lithium Manganese Dioxide Coin Cells	No difference
Battery Life (typical)	100 hours operational	No difference