June 30, 2021

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

Re: K210753
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: March 12, 2021
Received: March 15, 2021

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)*

K210753

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

AliveCor®

510(k) Summary for K210753

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	May 27, 2021

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., K183319, Triangle System (marketed as 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 submission) to obtain and analyze ECG signals. KardiaMobile 6L consists of KardiaMobile 6L Hardware (portable small wireless hardware with electrodes) and the Kardia 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 App on the MCP. KardiaMobile 6L displays thus record their ECG and additionally provides ECG analysis using the KardiaAI (K181823, K201985) ECG analysis suite, which includes the determinations of Atrial Fibrillation, Normal Sinus Rhythm, Bradycardia, Tachycardia, or Unclassified. 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. Patients can forward the recorded ECG to their HCP, who can review the ECG for rhythm and to measure the QT interval. The device is available for Over-the-Counter (OTC) purchase and for purchase with a prescription. The Kardia App is also comes in an alternate variant, called the KardiaStation App that is exclusively used within hospitals and clinics; this app is identical to the Kardia App with the exception of incorporating patient administration workflows.

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, technological characteristics and software as the K183319, Triangle System (marketed as "KardiaMobile 6L") predicate device. The difference between the two devices is labeling only, in that the subject device expands the use by HCPs to measure the QT interval in addition to the rhythm analysis application in the predicate. This expanded use has been analyzed and addressed through performance testing. The testing results showed that differences between the subject and predicate device do not raise different questions of safety or effectiveness. QT interval measurement is prescription use.

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

Feature	**AliveCor KardiaMobile 6L (Subject Device)**	**AliveCor KardiaMobile 6L (K183319) (Predicate Device)**
Product Code	DXH, DPS, QDA	DXH, DPS, QDA
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	Rhythm analysis only
Anatomical sites	Left hand fingers to right hand fingers Left hand fingers to right hand fingers and to left leg/knee	No difference
Available Algorithms (through KardiaAI K181823)	Atrial Fibrillation Noise Algorithm Normal Sinus Rhythm Tachycardia Bradycardia	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

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 and software, and the changes are to device labeling only, no bench testing was required.

Clinical Testing Summary [807.92(b)(2)]
Clinical performance testing was conducted to validate that a healthcare professional can review and measure the QT interval reliably using an ECG recorded using KardiaMobile 6L. The clinical evaluation compared KardiaMobile 6L 6-lead measurements (recorded in a sitting position) to an FDA-cleared gold standard 12-lead diagnostic ECG device (recorded supine) in 313 subjects. Subjects included both healthy volunteers and patients suspected of long QT syndrome or other genetic heart disease. ECG recordings from both the subject device and gold standard device were taken comparison. A core lab used to provide precise QT measurements for Thorough QT studies was utilized to measure the QT and heart-rate corrected QTc in each ECGs, in a randomized and blinded order, using standard measurement techniques. The comparative statistical analysis of this assessment determined that the QT interval measured using the subject device is equivalent to the interval measured from a commercial gold-standard diagnostic 12-lead ECG. The results of the testing demonstrated that the modifications to the KardiaMobile 6L labeling do not raise different questions of safety or effectiveness.

Conclusions [807.92(b)(3)]
KardiaMobile 6L has the same intended use as the predicate device, and the labeling differences do not raise different questions of safety or effectiveness. The labeling differences between the subject device and the predicate device have been clinically validated. Therefore, KardiaMobile 6L is substantially equivalent to the predicate device.