November 30, 2021

AliveCor, Inc.
Shani Frenkel
Regulatory Affairs Manager
444 Castro Street, Suite 600
Mountain View, California 94041

Re: K211668
Trade/Device Name: KardiaMobile Card
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Reciever
Regulatory Class: Class II
Product Code: DXH, DPS, QDA
Dated: November 3, 2021
Received: November 4, 2021

Dear Shani Frenkel:

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)*
K211668

Device Name
KardiaMobile Card System

Indications for Use *(Describe)*
The KardiaMobile Card System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The KardiaMobile Card 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 Card 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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510(k) SUMMARY

510(k) Notification K211668

GENERAL INFORMATION [807.92(a)(1)]

Applicant:
AliveCor, Inc.
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Mountain View, CA 94041
Phone: 650-396-8553
Fax: 650-282-7932

Contact Person:
Shani Frenkel
Regulatory Affairs Manager
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Mountain View, CA 94041
Phone: 650-396-8553
Email: ra@alivecor.com

Date Prepared: May 27, 2021

DEVICE INFORMATION [807.92(a)(2)]

Trade/Proprietary Name:
KardiaMobile Card 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)]

K191406 – AliveCor KardiaMobile System (Primary predicate)
K183319 – AliveCor Triangle System (Reference device)

510(k) SUMMARY

DEVICE DESCRIPTION [807.92(a)(4)]

The AliveCor KardiaMobile Card System is a single-channel ambulatory electrocardiogram (ECG) device that is intended to record, store, transfer, display, and analyze single-channel ECG rhythms in an ambulatory setting. The device utilizes the computing power of Apple iOS- and Google Android-based smartphones to obtain and analyze single-channel ECGs. 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 Card 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)]

The KardiaMobile Card System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The KardiaMobile Card 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 Card 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.

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

The KardiaMobile Card System device is similar to the primary predicate device in terms of principle of operation, technological and performance characteristics (mechanism of action, sterilization and shelf life), materials, software and anatomical site.

The design modifications of the KardiaMobile Card System that prompted this Special 510(k) relate to:

- **Change in the Technological Characteristics:** There is change in the technological characteristics related to the BLE data transmission method (instead of ultrasonic acoustics as utilized by the primary predicate device, KardiaMobile System K191406).
    - AliveCor's KardiaMobile 6L System (also known as Triangle System, K183319), which has also been determined to be substantially equivalent to the KardiaMobile System (K191406), will be used as a reference device for the BLE components related to the data transmission method of the KardiaMobile Card system.

- **Change in the Hardware Material and Dimensional Specifications**: There is a change in the hardware material for the device chassis from Acrylonitrile butadiene styrene (ABS) plastic to polyvinyl chloride (PVC). However, there is no change in electrode material. The KardiaMobile Card System will employ two dry electrodes made of Stainless Steel, which is the same material as used by the primary predicate device. There is a change in the subject device dimensional specifications.

These modifications do not raise different questions of safety or effectiveness. The KardiaMobile Card System has the same intended use and similar technological characteristics as the primary predicate device, the AliveCor KardiaMobile System (K191406), and utilizes the same Kardia app and KardiaAI platform cleared for the predicate device. No modifications were made to the Kardia app software's clinical functionalities with respect to ECG acquisition, display, and analysis because of this change since its prior clearance under K191406, K182396 and K201985.

PERFORMANCE DATA [807.92(b)]

The following bench testing were conducted, and results of the collective testing demonstrated that differences between the subject device and the predicate device do not raise different questions of safety or effectiveness and that the KardiaMobile Card System is substantially equivalent to the primary predicate KardiaMobile System.

- ECG acquisition and transmission were verified with applicable clauses of IEC 60601-2-47:2012 to assess potential differences in ECG measurement and transmission which may arise as a result of the use of BLE for ECG transmission. Bluetooth Coexistence Testing was also conducted to verify the performance of the KardiaMobile Card System with respect to ECG measurement and MCP connectivity in the intended use environment.
- A biocompatibility evaluation of the KardiaMobile Card hardware materials was conducted per the requirements of ISO 10993-1:2018 and in consideration of the FDA Guidance Document titled, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process" (September 4, 2020).
- Electrical safety and electromagnetic compatibility testing were performed to verify that the KardiaMobile Card hardware complies with the requirements of:
    - IEC 60601-1:2012 and ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance),
    - IEC 60601-1-2:2014 (Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances -Requirements and tests),
    - IEC 60601-2-47:2012 (Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems), and
    - IEC 60601-1-11:2015 (Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment).
- General hardware and system-level verifications were conducted to demonstrate that the subject device performs in accordance with its design specifications.

SUMMARY

AliveCor, Inc. considers the KardiaMobile Card device to be substantially equivalent to the legally marketed predicate KardiaMobile device cleared under K191406. The testing, performed in agreement with recommendations in relevant FDA guidance documents and compliance standards, demonstrates that the differences in hardware between the modified device and the predicate device do not raise different questions of safety or effectiveness and that the modified KardiaMobile Card device is substantially equivalent to the predicate KardiaMobile device for its intended use.