AliveCor, Inc.
% Prabhu Raghavan
Vice President of Regulatory Quality
AliveCor
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K183319
Trade/Device Name: Triangle System
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH, DPS, QDA
Dated: April 9, 2019
Received: April 10, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Acting Assistant Director
External Heart Rhythm and Rate Devices Team
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)*
K183319

Device Name
Triangle System

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

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

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510(k) SUMMARY

510(k) Notification K183319

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Mountain View, CA 94041
Phone: 650-396-8553
Fax: 650-282-7932

Contact Person:

Prabhu Raghavan
Vice President of Regulatory and Quality
Phone: 650-396-8553
Email: RA@alivecor.com.

Date Prepared:

April 8, 2019

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Triangle System

Generic/Common Name:

Telephone electrocardiograph transmitter and receiver

Classification:

21 CFR§870.2920, Transmitters and Receivers, Electrocardiograph, Telephone, Class II

Product Code:

DXH, DPS, QDA

510(k) SUMMARY

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

K142672 – AliveCor Heart Monitor (currently marketed as "KardiaMobile")

K181823 – AliveCor KardiaAI

DEVICE DESCRIPTION [807.92(a)(4)]

The Triangle System 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. The Triangle System provides output of one or six ECG leads by recording Lead-I and Lead-II simultaneously and derive Lead-III and unipolar limb leads aVR, aVF, and aVL for identifying cardiac arrhythmias. The device utilizes the computing power of iOS-based or Android-based smartphones (referred to as "Mobile Computing Platforms" (MCP) within this submission) to obtain and analyze ECG signals. The device consists of the Triangle Hardware (portable small wireless hardware with electrodes) and the Kardia app, which is installed on an MCP (i.e., iPhone or Android phone). The Triangle System is a new addition to AliveCor's ambulatory ECG devices that are intended to be used by lay users to record their ECG and obtain ECG analysis of Atrial Fibrillation, Normal Sinus Rhythm, Bradycardia, Tachycardia, or unclassified file. The Triangle System hardware transmits the ECG signal from the electrodes 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. The device is available for Over-the-Counter (OTC) purchase and for purchase with clinician prescription.

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

The Triangle System is intended to record, store and transfer one- and two-channel electrocardiogram (ECG) rhythms. In single channel mode, the Triangle System can record Lead-I. In two channel mode, the Triangle System can record Lead-I and Lead-II simultaneously and derive Lead-III and unipolar limb leads aVR, aVF and aVL. The Triangle 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 Triangle 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.

510(k) SUMMARY

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

Feature	Triangle System (subject device)	AliveCor Heart Monitor K142672
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
Anatomical sites	Left hand fingers to right hand fingers Left hand fingers to right hand fingers and to left leg/knee	Left hand fingers to right hand fingers Right hand fingers to left leg/knee
Available Algorithms	Atrial Fibrillation Noise Algorithm Normal Sinus Rhythm Tachycardia Bradycardia	Atrial Fibrillation
Data Acquisition: *Frequency Response*	 0.5Hz – 40Hz	 No difference
No. of ECG electrodes	Three (3) dry electrodes	Two (2) dry electrodes
No. of ECG channels	Single-channel and two-channel	Single channel only
Resolution	16 bits	No difference
Sample Rate	300 Samples/Second	No difference
Power Supply: *Battery* *Battery Life (typical)*	 1 Lithium Manganese Dioxide Coin Cells 100 hours operational	No difference
Leads	Lead-I, or Lead-I, Lead-II, Lead-III, aVL, aVR and aVF.	Lead-I or Lead-II
Hardware interface *Software interface*	Three-electrode sensor Apple iOS-based or Google Android-based software	Two-electrode sensor No difference
Communications	Bluetooth Low Energy	Ultrasonic Acoustics acquired by phone
Physical Specs: *Dimensions* *Weight*	 90 x 30 x 7mm 24 grams	 82 x 32 x 3.5mm 15 grams

SUBSTANTIAL EQUIVALENCE

The Triangle System subject device has the same intended use and similar technological characteristics as the AliveCor Heart Monitor predicate device. The differences in technological characteristics have 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.

PERFORMANCE DATA [807.92(b)]

All necessary non-clinical and clinical performance testing was conducted on the Triangle System to support a determination of substantial equivalence to the predicate device.

[807.92(b)(1)] Nonclinical Testing Summary:

All necessary performance testing was conducted on the Triangle System with passing results supporting the determination of substantial equivalence to the predicate device. This testing included the following:

- Verification of the device's specification
- Testing to software level of concern requirements
- Validation of KardiaAI integration
- Validation of BLE ECG transmission
- Human factors evaluation
- Evaluation to the following standards:
    - ISO 10993-1:2009 (CORR 2010), Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
    - IEC 60601-1:2012, 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 Compatibility - Requirements And Tests,
    - 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, and
    - IEC 60601-2-47:2012, Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems.

[807.92(b)(2)] Clinical Study Summary:

The performance of the Triangle System for recording a 6-lead ECG was validated in a clinical study. Overall, 44 subjects participated in the study, that included nearly equal numbers of healthy volunteers and arrhythmia patients. ECG recordings were taken simultaneously with both the Triangle device and gold standard 12-lead ECG device for comparison. Qualitative and quantitative analyses of equivalence were performed on the 44 pairs of ECGs.

For qualitative assessment, two board-certified electrophysiologists compared 6-lead ECG rhythm strips acquired from the Triangle device and the corresponding leads from the reference standard 12-lead ECG device for diagnostic equivalence. All paired recordings (100%, n=44 subjects), were deemed equivalent for assessing cardiac arrhythmias by both electrophysiologists. The results of the assessment determined that

the subject device records a 6-lead ECG that is qualitatively equivalent to the recordings of corresponding leads from a commercial gold standard 12-lead ECG device.

For quantitative equivalence, median beat cross correlation for Lead I and II and RMS error for all 6 limb leads were computed between the paired ECGs for each subject. This analysis was conducted on the unfiltered ECG output as well as the enhanced filtered (EF) ECG output. Triangle ECGs had a minimum correlation of 0.96 and a maximum RMS error of 47 μV as compared to the corresponding lead of the 12-lead ECG. The results of the quantitative analysis of the ECG recordings further confirmed that the Triangle device ECG has equivalent output to that of the gold standard 12-lead ECG device.

During this clinical study, no adverse events were observed.

SUMMARY

The Triangle System has the same intended use and similar technological characteristics as the AliveCor Heart Monitor predicate device. The differences in technological characteristics have been analyzed and addressed through performance testing which included non-clinical and clinical testing. The testing results show that differences between the subject and predicate device do not raise different questions of safety or effectiveness. The Triangle System is substantially equivalent to the predicate device.