November 16, 2017

Alivecor, Inc
% Anna Libman
Senior Manager, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K171816
Trade/Device Name: Kardia Band System
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH, DPS
Dated: October 11, 2017
Received: October12, 2017

Dear Anna Libman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171816

Device Name
Kardia Band System

Indications for Use *(Describe)*

The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.

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 K_____

GENERAL INFORMATION

Applicant:

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Applicant Contact Person:

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Date Prepared:

June 16, 2017

DEVICE INFORMATION

Trade Name:

Kardia Band 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

PREDICATE DEVICE(S)

- K142743 – AliveCor Heart Monitor (also known as Kardia Mobile)

510(k) SUMMARY

INDICATIONS FOR USE

The Kardia Band System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Kardia Band System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The Kardia Band System is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.

DEVICE DESCRIPTION

The Kardia Band 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 the Apple, Inc. Apple Watch to obtain and analyze single-channel ECG. The Kardia Band System consists of the Kardia Band Hardware (watchband), the Kardia watch app software (installed on the Apple Watch), and the Kardia phone app software (installed on the Apple iPhone). The Kardia Band System transmits the ECG signal from its electrode to the Kardia watch app on the Apple Watch to be analyzed and presented to the user. All ECGs are synced with the user's account.

Physical and Technological Characteristics of the Kardia Band System

Feature	Kardia Band System	Kardia Mobile K142743
Product Code	DXH, DPS	Same
Mechanism of Action	User completes circuit with skin contact and hardware transmits audio signal to MCP to convert and display ECG waveform	Same
Where used (intended use)	Mobile/active users at rest (ambulatory)	Same
Anatomical sites	Left hand fingers to right wrist or vice versa	Left hand fingers to right hand fingers
Data Acquisition: Frequency Response	 0.5 Hz – 40 Hz	Same
ECG channels	Single Channel	
Resolution	16 bit	
Sample Rate	300 Samples/Second	
Memory Capacity:	Essentially unlimited due to real-time transmission to MCP memory (size of ECG file is miniscule – kilobytes compared to device memory capacity – gigabytes)	Same

510(k) SUMMARY

Feature	Kardia Band System	Kardia Mobile K142743
Number of ECG Leads	Single lead, 2 electrodes	Same
Power Supply: Battery Battery Life (typical)	 1 Lithium Manganese Dioxide Coin Cells 100 hours operational	Same
User Interface: Primary Lead Data acquisition Hardware Software interface	 Lead I, Left to Right Ultrasonic acoustics Apple Watch Band and Sensor Apple iOS based software and Apple WatchOS based software	 Same Same iPhone Case and Universal Module Apple iOS based software
Physical Specs: Dimensions Weight	 24.5 x 24.5 x 6.5 mm 9 grams	 118 x 62 x 16.5 mm 40 grams
Prescribed:	Prescription and OTC	Same
Environmental: Operating Temp Storage Temp	 10 to 40 degrees C -20 to 60 degrees C	Same
Communications	Ultrasonic Acoustics acquired by watch	Ultrasonic Acoustics acquired by phone

SUBSTANTIAL EQUIVALENCE

The Kardia Band System is substantially equivalent to the previously cleared Kardia Mobile product (AliveCor Heart Monitor hardware and software (K142743), also known as Kardia Mobile). The new Kardia Band System has been redesigned to fit on an Apple Watch band and has the same intended use and similar technological characteristics as those of the predicate device. Differences in technological characteristics have been evaluated through performance testing, and therefore the proposed device is substantially equivalent to the predicate device.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the Kardia Band System to support a determination of substantial equivalence to the predicate device. This testing included testing to the following standards: 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*, and IEC 60601-2-47:2012 *Medical Electrical Equipment* --

510(k) SUMMARY

Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems. The collective results of the non-clinical testing demonstrate that the Kardia Band System meets the established specifications and complies with the aforementioned standards.

CLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Clinical performance testing was conducted to demonstrate that the AliveCor Kardia Band System generates rhythm strip data that meets the clinical quality requirements for accurate cardiac rhythm diagnosis.

The presented data shows very strong mathematical correlation and qualitative clinical equivalence. The study is sufficient to draw a conclusion of substantial equivalence based on meeting qualitative and quantitative acceptance criteria.

CONCLUSION

The results of both clinical and nonclinical testing demonstrate that the Kardia Band System is substantially equivalent to the predicate device.