DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 15, 2014

Alivecor, Inc.
Albert Boniske
Director of Regulatory Affairs
30 Maiden Lane, 6th Floor
San Francisco, California 94108

Re: K140933
Trade/Device Name: Alivecor Heart Monitor
Regulation Number: 21 CFR 870.2920
Regulation Name: Transmitters and Receivers, Electrocardiograph, Telephone
Regulatory Class: Class II
Product Code: DXH, DPS
Dated: July 9, 2014
Received: July 10, 2014

Dear Albert Boniske,

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.

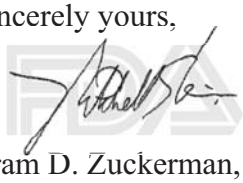
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 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 yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

AliveCor™

SECTION 4

INDICATIONS FOR USE STATEMENT

510(k) Number: K140933

Device Names: AliveCor Heart Monitor

Indications for Use:

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

Prescription Use X		Over-The-Counter Use X
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5

510(k) SUMMARY

510(k) Notification K140933

GENERAL INFORMATION

Applicant:
AliveCor, Inc.
30 Maiden Lane, 6th Floor
San Francisco, CA 94108

Contact Person:
Albert Boniske
Director of Regulatory Affairs
AliveCor, Inc.
Phone: 415-795-9811
Fax: 415-397-0440

Date Prepared:
April 9, 2014

DEVICE INFORMATION

Trade Name:
AliveCor Heart Monitor

Generic/Common Name:
Electrocardiograph

Classification:
21 CFR§870.2340, Electrocardiograph, Class II

Product Code:

DPS, DXH

PREDICATE DEVICE(S)

- K130921 – AliveCor Heart Monitor
- K052767 – AfibAlert
- K122184 – ECG Check

INDICATIONS FOR USE

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DEVICE DESCRIPTION

The AliveCor Heart Monitor (the device) is the next generation of trans-telephonic (transmission by telephone) single-lead ECG (electrocardiogram) event recorders. The device utilizes the processing power of a mobile computing platform (MCP) while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The device is placed on the chest or held by the user's hands to provide a single-channel ECG rhythm strip. Similar to other mobile ECG devices, the AliveCor Heart Monitor uses a proprietary method of data transmission using acoustic waves to communicate with the MCP where the waveform is stored, displayed, and analyzed for the presence of atrial fibrillation.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the AliveCor Heart Monitor. The AliveCor Heart Monitor operates using the same technological characteristics for the same intended use as its predicate devices. All devices record and store ECGs and indicate the presence of abnormalities in the recording. The nonclinical testing results demonstrate that any differences in the technological characteristics between the subject and predicate devices do not raise any new issues of safety or effectiveness. Thus, the AliveCor Heart Monitor is substantially equivalent to the predicate devices.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the AliveCor Heart Monitor to support a determination of substantial equivalence to the predicate devices. The non-clinical testing included software verification and atrial fibrillation (AF) algorithm validation. The AF algorithm was tested in accordance with AAMI/ANSI EC57. ECGs that were previously recorded using the AliveCor Heart Monitor and labeled by cardiologists were used to validate the performance of the AF algorithm. The collective results of the non-clinical testing demonstrate that the AliveCor Heart Monitor meets the established specifications necessary for consistent performance for its intended use.

CONCLUSION

The results of the nonclinical testing demonstrate that the AliveCor Heart Monitor is substantially equivalent to the predicate devices.