December 13, 2024

HeartBeam, Inc.
% Deborah Castillo
VP of Regulatory Affairs
Veranex, Inc.
224 Airport Parkway
Suite 250
San Jose, California 95110

Re: K231424
Trade/Device Name: HeartBeam AIMIGo(TM) System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, MWJ, DXH
Dated: December 11, 2024
Received: December 12, 2024

Dear Deborah Castillo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. Shih -S

Jennifer 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231424

Device Name

HEARTBEAM AIMIGO™ SYSTEM

Indications for Use *(Describe)*

The HeartBeam AIMIGo™ System is a portable non-invasive recorder intended to record, store, and transfer a patient's 3-Lead (in three-directions) electrocardiogram (ECG) acquired from 5 electrodes. The device is intended to be used by adult patients in either a clinical setting or at home. The device does not conduct cardiac analysis and can be used with an ECG Viewer software system for manual interpretation of non-life-threatening arrhythmias by a physician or healthcare professional.

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) Notification K231424

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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USA
Phone: 408-899-4443

Contact Person:

Deborah Castillo
VP of Regulatory Affairs
2118 Walsh Road, Suite 210
Santa Clara, CA, 95050
USA
Phone: 408-899-4443

Date Prepared: November 20, 2024

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:
HeartBeam AIMIGo™ System

Generic/Common Name:
Electrocardiograph

Classification:
Class II

Regulation:
21 CFR§870.2340

Product Codes:
Primary: DPS
Secondary: MWJ, DXH

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

Primary Predicate: AliveCor, Inc., KardiaMobile 6L (K210753)

Reference Device: VectraCor Inc., Universal Smart ECG, VectraPlex ECG (K173952)

DEVICE DESCRIPTION [807.92(a)(4)]

The HeartBeam AIMIGo™ System captures a 3-lead (in three-directions) electrocardiogram (ECG) recording of patients who have been prescribed a HeartBeam AIMIGo™ System for recording an ECG remotely. The HeartBeam AIMIGo™ System records and transmits the 3-lead ECG signal which can be displayed as rhythm strips on a compatible ECG viewer. The HeartBeam AIMIGo™ System does not provide any analysis of the ECG data nor provide any recommendation toward a clinical diagnosis and is not intended to be used with automated ECG analysis systems. It reports a series of 3-lead ECG rhythm strips for manual interpretation. The hardware platform is designed to be functional and effective with any compatible software designed for the purpose of displaying ECG waveforms for clinical review. The HeartBeam AIMIGo™ System will be provided by prescription only.

The system allows the patient (or their caregiver or healthcare provider) the capability to perform the following:

- Record a 3-lead (in three-directions) ECG with the recording device and accompanying mobile Patient Application
- Transmit the recorded 3-lead ECG signal to the cloud server, which can then be accessed by a clinician via the Clinician Portal for review and manual interpretation.

Filters applied may impact the ECG signal morphology, including significant attenuation of low-level atrial activity (P-waves / Flutter-waves), which may result in inability to discriminate certain types of arrhythmias (e.g., Atrial Fibrillation/Atrial Flutter).

The ECG report produced by HeartBeam AIMIGo is not intended for analysis of the T-wave or other morphological ECG evaluation.

The AIMIGo device is not intended for patients with tremors and/or those unable to place and maintain the device in the correct position for the duration of the recording.

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

The HeartBeam AIMIGo™ System is a portable non-invasive recorder intended to record, store, and transfer a patient's 3-Lead (in three-directions) electrocardiogram (ECG) acquired from 5 electrodes. The device is intended to be used by adult patients in either a clinical setting or at home. The device does not conduct cardiac analysis and can be used with an ECG Viewer software system for manual interpretation of non-life-threatening arrhythmias by a physician or healthcare professional.

SUBSTANTIAL EQUIVALENCE

The HeartBeam AIMIGo™ System Has the same intended use and similar physical characteristics and technological characteristics as the predicate device, the KardiaMobile 6L (K210753). The difference between the two devices is in the 3-lead signal data, which is similar to the reference device, the Universal Smart ECG/VectraPlex ECG from VectraCor, Inc (K173952). The differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the HeartBeam AIMIGo™ System is substantially equivalent to the Predicate Device.

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

Table 1 below shows the comparison of technological characteristics with the predicate devices.

Table 1: Comparison of Technological Characteristics with the Predicate Device

Device Name	HeartBeam AIMIGo™ System (Subject Device)	AliveCor KardiaMobile 6L (Primary Predicate Device)	Universal Smart ECG – VectraPlex ECG (Reference Device)	Rationale for Substantial Equivalence/ Comments
510(k) Number	K231424	K210753	K173952	-
Company	HeartBeam, Inc.	AliveCor, Inc	VectraCor, Inc	-
Regulation	21 CFR§870.2340	21 CFR§870.2340	21 CFR§870.2340	Same
Product Code	**DPS**, **DXH**, MWJ	**DPS**, **DXH**, QDA	**DPS**, MLD	Same
Class	II	II	II	Same
Intended Use / Indications for Use	The HeartBeam AIMIGo™ System is a portable non-invasive recorder intended to record, store, and transfer a patient's 3-Lead (in three directions) electrocardiogram (ECG) acquired from 5 electrodes. The device is intended to be used by adult patients in either a clinical setting or at home. The device does not conduct cardiac analysis and can be used with an ECG Viewer software system for manual interpretation of non-life-threatening arrhythmias by a physician or healthcare professional.	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.	The System is intended to derive, display and print a derived 12 lead ECG as well as the X, Y, Z leads from the acquisition of just 3 leads (5 electrodes). The System also has the capability to acquire the standard 12 lead ECG using the standard 10 electrodes and convert the ECG signal into a digital format. • The 12 lead interpretive software is a windows-based program intended to interpret electrocardiograms. The software receives, displays and stores a single, three or standard 12 lead simultaneous ECG recording, which is transmitted either locally or trans-telephonically from an ECG monitor using a proprietary digital data transmission protocol+. The device contains proprietary software algorithms to receive, store, analyze and interpret the 12 lead ECG signal only. • In 5 electrode mode, the System analyzes data from 3 leads (5 electrodes) and produces visual and audible alarms for ECG changes that may be consistent with 12-	Similar

Device Name	HeartBeam AIMIGo™ System (Subject Device)	AliveCor KardiaMobile 6L (Primary Predicate Device)	Universal Smart ECG – VectraPlex ECG (Reference Device)	Rationale for Substantial Equivalence/ Comments
			lead ECG signs of Acute Myocardial Ischemic Injury, including Acute Myocardial Infarction. This mode is not intended to be a sole means of diagnosis, but prompts the user to acquire a standard 12 lead ECG (using 10 electrodes) for interpretation by a physician when the Cardiac Electrical Biomarker (CEB®) is 95 or greater. Monitoring patients with a CEB® is only indicated for patients presenting with chest pain or other presumed anginal equivalents. • The interpretation software is only available for the standard 12 lead ECG utilizing the standard 10 electrodes. • The System is intended to be used by healthcare professionals, or trained personnel where ECG monitoring /acquisition is indicated for hospitals and/or clinics. • The System can be used within electro-surgical environments. • Device is for Adult use.	
Patient Population	Adults Only	Adults Only	Adults Only	Same
Use Environment	Clinical or Home Setting	Clinical or Home Setting	Clinical Setting Only	Same
Channel	3 channels.	1 or 2 Channels	3 or 12 channels.	Similar

Device Name	HeartBeam AIMIGo™ System (Subject Device)	AliveCor KardiaMobile 6L (Primary Predicate Device)	Universal Smart ECG – VectraPlex ECG (Reference Device)	Rationale for Substantial Equivalence/ Comments
Number of Electrodes	5 dry-electrodes	3 dry-electrodes	5 or 10 gel-electrodes	Similar
Recording Duration	30 seconds	Minimum of 30 seconds	Minimum of 10 seconds	Same
Data Acquisition Frequency Response	0.5 Hz to 40 Hz	0.5 Hz to 40 Hz	0.05 to 175Hz ± 3dB	Same
Single Use	No	No	No	Same
Prescription Use/ Over the Counter	Prescription Use	Prescription Use and OTC use	Prescription Use	Same
Power Source	Battery, 1 Lithium-ion rechargeable.	Battery, 1 Lithium Manganese Dioxide Coin Cells (CR2016)	Powered by a PC USB or PS/2 port	Similar

PERFORMANCE DATA [807.92(b)]:

All necessary bench testing was conducted on the HeartBeam AIMIGo™ System to support a determination of substantial equivalence to the Predicate Device.

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

The nonclinical bench testing included:

- Software verification and validation per the requirements of EC 62304:2006 (Medical device software – Software life cycle processes).
- ECG acquisition and transmission performance were verified with applicable clauses of IEC 60601-2-47:2012.
- A biocompatibility evaluation of the HeartBeam AIMIGo™ 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).
- Electromagnetic Compatibility and Electrical Safety testing were performed to verify that the AIMIGo™ hardware complied 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)
- Human Factors and Usability testing in accordance with IEC 62366-1 (Medical devices – Part 1: Application of usability engineering to medical devices).
- General hardware and system-level verifications were conducted to demonstrate that the subject device performs in accordance with its design specifications.

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the HeartBeam AIMIGo™ System meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the HeartBeam AIMIGo™ System does not raise different questions

of safety or effectiveness for recording a patient's vector electrocardiogram when compared to the Predicate Device.

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

Clinical testing was conducted to support device performance in this 510(k) submission:

- Pivotal Study: The objective of this study was to demonstrate the clinical equivalence of ECG waveforms between AIMIGo 3-L VECG (investigational device) recordings and reference standard 12-L ECG for interpretation of non-life-threatening arrhythmias . All study endpoints were met, and the information provided supports that device performance is substantially equivalent to the predicate.
- Device Positioning Validation Study: This was a prospective single-arm clinical trial to validate that within a predetermined range of distance, direction and orientation with respect to the recommended position per labeling, the output signal characteristics of the AIMIGo 3L VECG remain unaffected when compared to a standard 12L ECG signal recorded simultaneously, for interpretation of non-life-threatening arrhythmias. All study endpoints were met, and the information provided supports that device performance is substantially equivalent to the predicate.

CONCLUSIONS [807.92(b)(3)]:

Based on the results from the tests performed in support of the HeartBeam AIMIGo™ System, it is concluded that the Proposed Device is substantially equivalent to the legally marketed Predicate Device.

SUMMARY

The HeartBeam AIMIGo™ System is substantially equivalent to the Predicate Device.