December 8, 2025

HeartBeam, Inc.
Deborah Castillo
VP of Regulatory Affairs
2118 Walsh Road, Suite 210
Santa Clara, California 95110

Re: K250258
Trade/Device Name: HeartBeam AIMIGo with 12-L ECG Synthesis Software System
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH, MWJ, DPS
Dated: October 20, 2025
Received: October 20, 2025

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
OHT2: 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)*
K250258

Device Name

HEARTBEAM AIMIGo™ SYSTEM WITH 12-L ECG SYNTHESIS SOFTWARE

Indications for Use *(Describe)*

HEARTBEAM AIMIGo SYSTEM:
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.

HEARTBEAM 12-L ECG SYNTHESIS SOFTWARE:
The HeartBeam 12-L ECG Synthesis Software synthesizes a 12-L ECG from the HeartBeam AIMIGo 3-Leads (in three-directions) recording device, producing a visual 12-L ECG representation that is similar, but not identical, to the same leads of a standard diagnostic 12-L ECG.

The synthesized 12-L ECG output is solely intended for manual assessment of normal sinus rhythm and the following non-life-threatening arrhythmias: sinus arrhythmia, sinus tachycardia, sinus bradycardia, atrial premature complexes, atrial fibrillation, and ventricular premature complex. The synthesized 12-L ECG output is not intended for the assessment of any other arrhythmia or conditions (including but not limited to: other atrial arrhythmias, ventricular arrhythmias, hypertrophy, conduction disorders, myocardial infarction or ischemia, pacemaker functions, localization of arrhythmia foci, ECG wave abnormalities, and/or any other disorder). The software does not conduct cardiac analysis and is not intended to replace a standard 12-L ECG. The 12-L ECG Synthesis Software is intended for adult use only.

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.

510(k) Notification K250258

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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USA
Phone: 408-899-4443

Contact Person:

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Santa Clara, CA, 95050
USA
Phone: 408-899-4443

Date Prepared: November 17, 2025

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

HeartBeam AIMIGo™ System with 12-L Synthesis Software

Generic/Common Name:

Electrocardiograph

Classification:

Class II

Regulation:

21 CFR§870.2920

Product Codes:

Primary: DXH
Secondary: DPS, MWJ

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

Primary Predicate:

- PaceArt Associates, L.P., HomeTrak Plus EASI Event Recorder System (K982090)

Reference Devices:

- HeartBeam AIMIGo™ System (K231424)

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 is 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.

This submission includes a modification to the HeartBeam System involving the addition of a new software feature, the HeartBeam 12-L Synthesis Software. Like the HeartBeam AIMIGo system, the patient-activated recording of a 3-L ECG is obtained and the HeartBeam 12-L Synthesis Software can synthesize a 12-L ECG signal from the 3-lead ECG signal recorded from the HeartBeam AIMIGo Device of the cleared system. The synthesized 12-L ECG output signal is intended to be an adjunct set of ECG information that complements but does not replace a standard 12-L ECG, to aid in the manual assessment of non-life-threatening arrhythmias.

The synthesized 12-L ECG signal has not been studied or evaluated for safe and effective use for other cardiac conditions outside of manual non-life-threatening arrhythmias and is contraindicated for the assessment of any urgent, serious, or life-threatening conditions or arrhythmias.

The new software works with the HeartBeam system, which retains all functionalities and performance characteristics of the previously cleared system. No changes to the hardware, intended use, or fundamental technological characteristics were made to incorporate the new

software. Additionally, the synthesis software works with the standard 12-L ECG system, the EDAN SE-1515 DX-12. The EDAN SE-1515 DX-12 systems provide a patient's compatible standard 12-L ECG signal, which is used as one of the inputs for the synthesis software to create the personalized transformation matrix for each patient.

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

HeartBeam AIMIGo System:

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.

HeartBeam 12-L Synthesis Software

The HeartBeam 12-L ECG Synthesis Software synthesizes a 12-L ECG from the HeartBeam AIMIGo 3-Leads (in three-directions) recording device, producing a visual 12-L ECG representation that is similar, but not identical, to the same leads of a standard diagnostic 12-L ECG.

The synthesized 12-L ECG output is solely intended for manual assessment of normal sinus rhythm and the following non-life-threatening arrhythmias: sinus arrhythmia, sinus tachycardia, sinus bradycardia, atrial premature complexes, atrial fibrillation, and ventricular premature complex. The synthesized 12-L ECG output is not intended for the assessment of any other arrhythmia or conditions (including but not limited to: other atrial arrhythmias, ventricular arrhythmias, hypertrophy, conduction disorders, myocardial infarction or ischemia, pacemaker functions, localization of arrhythmia foci, ECG wave abnormalities, and/or any other disorder). The software does not conduct cardiac analysis and is not intended to replace a standard 12-L ECG. The 12-L ECG Synthesis Software is intended for adult use only.

SUBSTANTIAL EQUIVALENCE

The HeartBeam AIMIGo™ System with 12-L ECG Synthesis Software is substantially equivalent to the Predicate Device, the HomeTrak Plus EASI Event Recorder System (K982090). These devices share the same intended use in the sense that the fundamental parts of the system allow the capability to record, store, and transfer a patient's 3-L ECG signal, which is used to create synthesized 12-L ECG signals. Both the 3-L ECGs and synthesized 12-L ECGs are intended for manual assessment of non-life-threatening arrhythmias. Moreover, the predicate and proposed device systems have comparable technological features. The methods used by the new software to achieve 12-L synthesis are similar to the methods used by the predicate devices (i.e. linear transformation matrices). Performance testing data support the software's capabilities

to achieve its intended use and demonstrate that the technological differences do not raise new questions about device safety or effectiveness.

The new software works with the Reference Device, the HeartBeam AIMIGo™ System (K231424) as the12-L Synthesis Software synthesizes a 12-L ECG signal from the 3-lead ECG signal recorded from the HeartBeam AIMIGo Device of the Reference Device system. The new software works with the HeartBeam system, which retains all functionalities and performance characteristics of the previously cleared system. No changes to the hardware, intended use, or fundamental technological characteristics were made to incorporate the new software, and thus both systems share these identical components.

Based on the above, the HeartBeam AIMIGo™ System with 12-L Synthesis Software 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 intended use and technological characteristics with the Predicate and Reference Devices.

Table 1: Comparison of Technological Characteristics with the Predicate Device

Device Name	HeartBeam AIMIGo™ System with 12-L Synthesis Software (Subject Device)	HomeTrak Plus EASI Event Recorder System (Primary Predicate Device)	HeartBeam AIMIGo System (Reference Device)	Rationale for Substantial Equivalence/ Comments
510(k) Number	K250258	K982090	K231424	-
Company	HeartBeam, Inc.	PaceArt Associates, L.P.	HeartBeam, Inc.	-
Classification	**21 CFR 870.2920**	**21 CFR 870.2920**	**21 CFR 870.2920**	**Same.**
Device Identification	Telephone electrocardiograph transmitter and receiver	Telephone electrocardiograph transmitter and receiver	Telephone electrocardiograph transmitter and receiver	**Same.**
Product Code	**DXH**, DPS, MWJ	**DXH**	**DXH**, DPS, MWJ	**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. The HeartBeam 12-L ECG Synthesis Software synthesizes a 12-L ECG from the HeartBeam AIMIGo 3-Leads (in three-directions) recording device, producing a visual 12-L ECG representation that is similar, but not identical, to the same leads of a standard diagnostic 12-L ECG. The synthesized 12-L ECG output is solely intended for manual assessment of normal sinus rhythm and the following non-life-threatening arrhythmias: sinus arrhythmia, sinus tachycardia, sinus bradycardia, atrial premature complexes, atrial fibrillation, and ventricular premature complex. The	The HomeTrak Plus Cardiac Twelve-Lead Event Recorder is a patient-activated ambulatory cardiac event monitor and associated central-station receiving equipment which are to be used for recording infrequent and elusive heart arrhythmias and transmitting them by telephone at a later time to a central analysis center. It records three electrocardiographic leads (3-Lead ECG) and derives 12 electrocardiographic leads (12-L ECG) from the three transmitted.	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.	**Same.** The HeartBeam System with 12-L ECG Synthesis Software has the same intended use as the HomeTrak Plus Cardiac 12-Lead Event recorder in that both systems record 3-Lead ECGs and derive a 12-L ECG from these signals. Both systems also transmit the signals (either recorded 3-Lead or derive 12-lead) for display and review by a physician at a later time. Both systems are also intended to be used for arrhythmia assessment only, as detailed in their corresponding Indications for Use statements. The Reference system, K231424, is being updated with the 12-L Synthesis SW feature to allow display of a synthesized 12-L ECG. Both the Reference and Subject device ECG outputs are intended to be used by adult patients in either a clinical setting or at home. Both ECG output signals are intended to be used for manual interpretation of non-life-threatening arrhythmias by a physician or healthcare professional. Neither system conducts cardiac analysis. The minor differences in the indications statement language do not constitute a new intended use, nor raise new

Device Name	HeartBeam AIMIGo™ System with 12-L Synthesis Software (Subject Device)	HomeTrak Plus EASI Event Recorder System (Primary Predicate Device)	HeartBeam AIMIGo System (Reference Device)	Rationale for Substantial Equivalence/ Comments
	synthesized 12-L ECG output is not intended for the assessment of any other arrhythmia or conditions (including but not limited to: other atrial arrhythmias, ventricular arrhythmias, hypertrophy, conduction disorders, myocardial infarction or ischemia, pacemaker functions, localization of arrhythmia foci, ECG wave abnormalities, and/or any other disorder). The software does not conduct cardiac analysis and is not intended to replace a standard 12-L ECG. The 12-L ECG Synthesis Software is intended for adult use only.			questions about device safety and effectiveness.
Patient Population	Adults Only	Adults Only	Adults Only	**Same.**
Use Environment	Clinical or Home Setting	Clinical or Home Setting	Clinical or Home Setting	**Same.**
Number of Electrodes	The HeartBeam AIMIGo™ Device with embedded 5-dry electrodes ("AIMIGo Device")	5 wet/gel electrodes	The HeartBeam AIMIGo™ Device with embedded 5-dry electrodes ("AIMIGo Device")	**Similar.** Both the HeartBeam systems use dry electrodes to acquire and record the 3-L ECGs. While the Predicate Device, HomeTrak System, uses wet-electrodes to acquire and record the 3-L ECGs, both the Proposed and Predicate systems used clinical and non-clinical testing to validate the output performance to ensure signal quality and noise is accounted for. The testing conducted on the HeartBeam system with 12-L synthesis software demonstrate the accuracy of the synthesized 12-L ECG output signals is acceptable for the same intended use within the labeled specifications. Thus, the differences do not raise different questions of safety or effectiveness.
Electrode Placement/Position on Patient Body	5 electrodes: Two (2) Chest & two (2) Left Hand Fingers to Right Hand Fingers and (1) RLD – right leg drive electrode.	5 electrodes – Using the EASI configuration: **E** (**Electrode on Chest**): Placed over the lower part of the sternum at the level of the fifth intercostal space.	5 electrodes: Two (2) Chest & two (2) Left Hand Fingers to Right Hand Fingers and (1) RLD – right leg drive electrode.	**Similar.** Both the HeartBeam systems use the identical electrode placement/positioning on the body to acquire and record the 3-L ECGs.

Device Name	HeartBeam AIMIGo™ System with 12-L Synthesis Software (Subject Device)	HomeTrak Plus EASI Event Recorder System (Primary Predicate Device)	HeartBeam AIMIGo System (Reference Device)	Rationale for Substantial Equivalence/ Comments
		A (**Anterior Left Electrode**): Positioned on the left mid-axillary line at the same horizontal level as the E electrode (fifth intercostal space). **S** (**Superior Electrode on Chest**): Located at the manubrium of the sternum (near the sternal notch). **I** (**Inferior Right Electrode**): Positioned on the right mid-axillary line at the level of the fifth intercostal space. **Ground Electrode:** Typically placed in a neutral location (e.g., **right lower Abdomen**, or Right torso)		While the HomeTrak System uses the specific EASI electrode configuration, both systems have upper and lower chest electrodes, left and right limb placement electrodes, and a fifth, neutral electrode. Both systems also used clinical and non-clinical testing to validate the output performance. The testing conducted on the HeartBeam system with 12-L synthesis software demonstrate the accuracy of the synthesized 12-L ECG output signals from the recorded 3-L ECG from this electrode placement. Therefore, the performance is acceptable for the same intended use within the labeled specifications. Thus, the differences do not raise different questions of safety or effectiveness.
ECG Viewer Leads Display Capability	3-Lead ECG or synthesized 12-Lead ECG in Cloud ECG Viewer	3-L ECG or derived 12-L ECG via Central Analysis Center	3-Lead ECG only in Cloud ECG Viewer	**Similar.** In the Predicate, the HomeTrak System, the central analysis center serves as the access point for a physician to view and assess either the 3-L ECG or derived 12-L ECG signals. The differences do not raise different questions of device safety or effectiveness, as the usability is the same (i.e. to view and assess the ECG signals).
Handheld HeartBeam AIMIGo Device Charging Method & Power Source	The HeartBeam AIMIGo™ Charging Dock ("Charging Dock") to charge a (1) rechargeable, Lithium-ion Battery	Not specified.	The HeartBeam AIMIGo™ Charging Dock ("Charging Dock") to charge a (1) rechargeable, Lithium-ion Battery	**Similar.** Both the HeartBeam systems use the same charging dock and rechargeable battery. While the HomeTrak system does not appear to need or use a battery or charging dock, given the same battery and charging dock have already been cleared and tested under the Reference Device system, the differences in this technological features do not raise new questions of safety and effectiveness.

Device Name	HeartBeam AIMIGo™ System with 12-L Synthesis Software (Subject Device)	HomeTrak Plus EASI Event Recorder System (Primary Predicate Device)	HeartBeam AIMIGo System (Reference Device)	Rationale for Substantial Equivalence/ Comments
Number of Channels/Leads Recorded	3 channels/Leads	3 channels/Leads	3 channels/Leads	**Same.**
Frequency Response	0.5 Hz to 40 Hz ± 3dB	Not specified.	0.5 Hz to 40 Hz ± 3dB	**Similar.** Although not specified by the Predicate System, this feature is identical between the Subject and Reference Device. Testing of the system for both the Subject and Predicate Device show acceptable performance for their intended use and thus supports substantial equivalence.
Recording Duration	30 seconds	Not specified.	30 seconds	**Similar.** Although not specified by the Predicate System, the duration of recording does not impact device safety or effectiveness. This feature is identical between the Subject and Reference Device. Testing of the system for both the Subject and Predicate Device show acceptable performance for their intended use and thus support substantial equivalence.
Synthesized Leads	All 12-Leads	All 12-Leads	Feature Not Available	**Same.** Both the Subject and Predicate systems have a 12-L ECG Synthesis SW feature that uses the recorded reduced lead-set 3-L ECG signals to derive all 12-Lead ECG output signals. Both systems derive all 12-leads. Through the acceptable test methods of SW V&V and full clinical validation test results, HeartBeam demonstrates that this new feature does not raise different questions of safety and effectiveness, and the performance of the synthesized 12-L ECG signal of the HeartBeam System is substantially equivalent to the Predicate device for the same intended use and indications.
Clinician User Interface	Cloud-Based Clinician Portal	Central Analysis Center	Cloud-Based Clinician Portal	**Similar.** The Predicate Device uses the Central Analysis Center for display and review of

Device Name	HeartBeam AIMIGo™ System with 12-L Synthesis Software (Subject Device)	HomeTrak Plus EASI Event Recorder System (Primary Predicate Device)	HeartBeam AIMIGo System (Reference Device)	Rationale for Substantial Equivalence/ Comments
				the transmitted 3-L ECG and derived 12-L ECG for physician review. The HomeTrak System uses the central analysis center to serve as the access point for a physician to view and assess either the 3-L ECG or derived 12-L ECG signals. In a similar fashion, the Subject Device uses the Clinical Portal for this purpose. The differences do not raise different questions of device safety or effectiveness, as the usability is the same (i.e. to view and assess the ECG signals). The cloud-base Clinical Portal in the Subject device is the same as the Clinician Portal of the Reference Device system, which has been updated to accommodate access to the synthesized 12-L ECG recordings and display for clinical review.
Data Transfer Method Between AIMIGo Device and Mobile Application	Wireless (Bluetooth/ BLE) communication between the patient Mobile Application and the AIMIGo device	Cable-based connection.	Wireless (Bluetooth/BLE) communication between the patient Mobile Application and the AIMIGo device.	**Similar.** The Predicate HomeTrak device uses electrode cables to acquire signals. The HeartBeam system uses Wi-Fi connection identical to the Reference Device system, and HeartBeam has ensured that proper transmission have been evaluated and tested to meet current standards and regulations.
Single Use	No.	No.	No.	**Same.**
Prescription Use/ Over the Counter	Prescription Use.	Prescription Use.	Prescription Use.	**Same.**

PERFORMANCE DATA [807.92(b)]:

All necessary bench testing was conducted on the HeartBeam AIMIGo™ System with 12-L Synthesis Software 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) and in accordance with FDA Guidance Document entitled, "General Principles of Software Validation," issued January 11, 2002
- Human Factors and Usability testing in accordance with IEC 62366-1 (Medical devices – Part 1: Application of usability engineering to medical devices) and FDA's Human Factors Guidance, *Applying Human Factors and Usability Engineering to Medical Devices, issued on February 3, 2016*.
- Cybersecurity Testing has been conducted in accordance with section 524B(b)(2) of the Federal Food, Drug, and Cosmetic Act, and FDA guidance "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*," issued *on June 27, 2025.*
- General 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 design of the HeartBeam AIMIGo™ System with 12-L Synthesis Software meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the HeartBeam AIMIGo™ System with 12-L Synthesis Software does not raise different questions of safety or effectiveness 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. The studies below were conducted in a population consistent with the subject device's indications for use:

- Pivotal Study: The objective of this U.S. study was to validate the AIMIGo 12-L ECG Synthesis Software by demonstrating the clinical equivalence between the synthesized 12-L ECG waveforms generated by the AIMIGo 12-L ECG Synthesis Software (investigational device) and reference standard 12-L ECG for interpretation of non-life-threatening arrhythmia. All study endpoints were met, and the information provided supports that device performance is substantially equivalent to the predicate. A total of 127 patients were included in the study population. This included data from 41.7% Females, 58.3% Males, and approximately 74% White/Caucasian, 3% Hispanic/Latino, 0.8% Asian, 18% Black, and 4% other ethnic group. The age distribution consisted of approximately 29% of patients under the age of 65 years old, 71% of patients that were 65 years or older, and a median age of 69 years old. For BMI measures, approximately 20% of patients had a BMI of less than 25, and 80% of patients had a BMI of 25 or greater.

- Device Positioning Validation Study: This was a prospective single-arm supplemental 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 12-L ECG Synthesis Software 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. A total of 45 patients were included in the study population. This included data from approximately 36% Females, 64% Males, and approximately 86% White/Caucasian, 7% Asian, and 7% Black. The age distribution consisted of approximately 78% of patients under the age of 65 years old, 22% of patients that were 65 years or older, and a median age of 51 years old. For BMI measures, approximately 47% of patients had a BMI of less than 25, and 53% of patients had a BMI of 25 or greater.

CONCLUSIONS [807.92(b)(3)]:

Based on the results from the tests performed in support of the HeartBeam AIMIGo™ System with 12-L Synthesis Software, it is concluded that the Subject Device is substantially equivalent to the legally marketed Predicate Device.