July 22, 2025

Cardiosense, Inc.
Arezou Azar
VP, Compliance
400 N Aberdeen St.
Suite 900
Chicago, Illinois 60642

Re: K243566
Trade/Device Name: CardioTag
Regulation Number: 21 CFR 870.2320
Regulation Name: Ballistocardiograph
Regulatory Class: Class II
Product Code: DXR, DRG, DPS, MWI
Dated: June 17, 2025
Received: June 17, 2025

Dear Arezou Azar:

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.

Submission Number *(if known)*

K243566

Device Name

CardioTag™

Indications for Use *(Describe)*

The CardioTag device is a tool that can be used to record, display and transfer vibrational waveforms produced by the heart contractions and transmitted to the chest as well as single-channel electrocardiogram (ECG) rhythms and heart rate. It also measures pulse waveform and pulse rate by photoplethysmograph (PPG). The CardioTag may be used as a tool to measure the timing of the aortic valve opening and closing in the cardiac cycle. The CardioTag is intended for spot-checking of adult patients in clinics or at home under the care of a physician. The data from the CardioTag is intended for use by healthcare professionals as an aid to diagnosis and treatment.

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

I. SUBMITTER

Cardiosense, Inc.
400 N Aberdeen St., Suite 900
Chicago, IL 60642

Contact Person: Arezou Azar, Ph.D.
VP Compliance (Regulatory, Quality, Clinical) and Program Management
email: arezou@cardiosense.com

Phone: (650) 804-0285

Date Prepared: November 15, 2024

II. DEVICE

Name of Device: CardioTag™
Common or Usual Name: Ballistocardiograph or seismocardiogram (SCG)
Classification Name: Ballistocardiograph (21 CFR 870.2320)
Regulatory Class: II
Product Code: DXR (primary); DRG, DPS, MWI

III. PREDICATE DEVICE

Primary: HeartForce Medical, dBG Digital Ballistocardiograph, K081603
Secondary: Meridian, McPulse Photoelectric Plethysmograph, K023238

IV. DEVICE DESCRIPTION

The CardioTag device consists of a rechargeable wearable that is responsible for collecting raw cardiac signals from a single patient, and produces a spot-check report of a patient's electrocardiogram (ECG), photoplethysmogram (PPG), and seismocardiogram (SCG) signals and heart rate. To generate the report, the user places the wearable on the sternum and starts a 2 minute recording session for waveform output and heart rate /pulse rate calculation. The wearable contains electrodes to measure single-lead ECG, light sources and optical sensor arrays to measure PPG, and an accelerometer to measure vibrational waveforms from the heart's contractions transferred to the chest wall (SCG). Sensor data is then transferred for storage and processing (e.g. to a cloud-based backend). The backend uses the recording to calculate heart rate and pulse rate and then visualizes the waveforms and heart rate in the format of a downloadable PDF report for the clinician. The SCG signal is intended to be used for manual interpretation by the clinician in conjunction with other information from the device. The device

may be used as a tool to measure the timing of the aortic valve opening and closing in the cardiac cycle.

V. INDICATIONS FOR USE

> *The CardioTag device is a tool that can be used to record, display and transfer vibrational waveforms produced by the heart contractions and transmitted to the chest as well as single-channel electrocardiogram (ECG) rhythms and heart rate. It also measures pulse waveform and pulse rate by photoplethysmograph (PPG). The CardioTag may be used as a tool to measure the timing of the aortic valve opening and closing in the cardiac cycle. The CardioTag is intended for spot-checking of adult patients in clinics or at home under the care of a physician. The data from the CardioTag is intended for use by healthcare professionals as an aid to diagnosis and treatment.*

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Both the subject device and predicates have the same intended use.

The subject device combines the outputs of the primary and secondary predicate devices as an all-in-one solution. The subject and primary predicate are aligned in that they are both reusable, battery powered devices placed on the chest via adhesives, perform spot checks (i.e. non-continuous measurements), and output ECG and vibrational waveforms in reports. The subject device and secondary predicate are similar in that they are battery powered, reusable devices that are used for spot-check measurements (i.e. non-continuous measurement), and both output PPG waveforms and use PPG as an input into heart rate calculations.

Minor technological differences have been addressed through risk management, bench-testing, clinical testing, and application of FDA-Recognized standards and, thus, do not raise new questions of safety and effectiveness.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the CardioTag device was conducted in accordance with the FDA guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, September 2023, and International Standard ISO 10993-1 *Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process*, as recognized by FDA.

Patient-contacting parts of the device were subjected to the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The CardioTag has Limited (<24 hrs) contact duration with (surface) intact skin.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety, EMC, and wireless coexistence testing were conducted on the CardioTag device. The device complies with the following standards:

Basic Safety and Performance

- Basic safety and Essential Performance
- Defibrillation – Proof Applied Parts (Differential Mode)
- Proof Applied Parts (Common Mode)

Electromagnetic Compatibility
Electrical safety and EMC testing was performed to applicable standards, including EMC/RF disturbances and immunity.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, November 2021.

Performance Testing

Bench-testing (non-clinical) was conducted for ECG, PPG, SCG functions to confirm that the following functions met specifications:

- ECG Validation
- PPG Validation
- SCG Validation

Animal Studies
No animal studies were undertaken to support substantial equivalence.

Clinical Studies
The CardioTag device has been clinically tested and validated in the US. Substantial equivalence was based in part on the clinical study. The subjects were recruited based on US demographics to present proper race and ethnicity to ensure diverse representation.

The primary endpoints for the CardioTag study were all met. The study results demonstrated that the CardioTag performs at an acceptable level when compared to commercially available devices with high accuracy.

VIII. CONCLUSIONS

The subject and predicate devices have the same Intended Use and similar technological characteristics. Bench-testing, biocompatibility, electrical safety and EMC, and clinical studies demonstrate that the differences in technological characteristics do not raise new questions of safety and effectiveness. As such, the CardioTag is substantially equivalent to the predicate devices.