May 22, 2026

Cardiosense, Inc.
Arezou Azar
Chief Regulatory and Compliance Officer
400 N Aberdeen St.
Suite 1050
Chicago, Illinois 60642

Re: DEN250057
Trade/Device Name: PCWP Analysis Software
Regulation Number: 21 CFR 870.1150
Regulation Name: Software device system for estimation of cardiac pressures
Regulatory Class: Class II
Product Code: SIF
Dated: November 17, 2025
Received: November 17, 2025

Dear Arezou Azar:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the PCWP Analysis Software, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> PCWP Analysis Software is intended to noninvasively estimate pulmonary capillary wedge pressure (PCWP) and identify patients with a PCWP above or below 18mmHg, for patients diagnosed with heart failure with reduced ejection fraction (HFrEF) and New York Heart Association (NYHA) Functional Class II, III, IV symptoms. The hemodynamic data will be used by qualified healthcare professionals in conjunction with other standard of care parameters to evaluate heart failure patients.
>
> The results of PCWP Analysis Software are intended to be used under the supervision of a qualified healthcare professional in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the qualified healthcare professional's judgment. Patient management decisions should not be made solely on the results of the PCWP Analysis Software. The device is only for prescription use.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the PCWP Analysis Software, and substantially equivalent devices of this generic type, into Class II under the generic name software device system for estimation of cardiac pressures.

FDA identifies this generic type of device as:

> **Software device system for estimation of cardiac pressures.** A software device system for estimation of cardiac pressures is a prescription-only device that uses software algorithms to analyze one or more non-invasive physiologic signals or parameters to estimate a cardiac pressure (e.g. pulmonary capillary wedge pressure, left ventricular end diastolic pressure, or pulmonary artery pressure). The device system may contain hardware sensors. This device system is intended for adjunctive use with patient information and is not intended to independently direct therapy. This device system is not intended to estimate systemic, vascular blood pressure.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On November 17, 2025, FDA received your De Novo requesting classification of the PCWP Analysis Software. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the PCWP Analysis Software into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the PCWP Analysis Software can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Measures
Delayed or incorrect treatment due to user misinterpretation or overreliance	Usability assessment Labeling
Inaccurate pressure estimation leading to incorrect treatment or diagnosis	Clinical performance testing Software verification, validation, and hazard analysis Labeling Postmarket monitoring
Delayed or incorrect treatment due to no output, indeterminate output, or erroneous output as a result of software malfunction or algorithm processing error	Clinical performance testing Software verification, validation, and hazard analysis Labeling Postmarket monitoring

In combination with the general controls of the FD&C Act, the software device system for estimation of cardiac pressures is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be met:
  (i) Agreement of the measure(s) with the reference measure(s) must be assessed across the clinically relevant physiological range as well as the full physiological range using performance metrics relevant to the device output. All performance metrics must include 95% confidence intervals;
  (ii) The data set must be representative of the intended use population for the device. Any selection criteria or limitations of the samples must be fully described and justified; The study must include representation across key demographic subgroups (race, ethnicity, sex, age) and relevant clinical characteristics; and
  (iii) Data must be provided within the clinical study or equivalent datasets to demonstrate the consistency of the output and representativeness of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment. The study must report any rate(s) of indeterminate output across demographic groups.

(2) Software verification, validation, and hazard analysis must be performed. Software documentation must include:
  (i) A full characterization of technical parameters of the software, including any algorithms or models used, all inputs and outputs for the software, and the supported patient population;
  (ii) Description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications;
  (iii) Specification of acceptable incoming sensor data quality control measures; and
  (iv) Data documentation describing any training, tuning, or validation datasets used in algorithm development.

(3) Usability assessment must be provided to demonstrate that risk of misinterpretation of the device output is appropriately mitigated.

(4) Labeling must include the following:
  (i) A summary of the clinical performance testing with the device, including:
    (A) Objective performance measures reported with 95% confidence intervals; and
    (B) A description of the patient population studied (including age, sex, race or ethnicity, relevant clinical conditions and comorbidities).
  (ii) Information for interpretation of the output must include:
    (A) A description of what the device measures and outputs to the user;
    (B) Warnings identifying sensor reading acquisition factors that may impact measurement results; and
    (C) A warning(s) that the device output is only for adjunctive use.

(5) The device manufacturer must develop and implement a postmarket performance management plan that ensures regular assessment of the generalizability and device performance in the intended patient population in real-world use. The plan must include:
  (i) Data collection, analysis methods, and procedures for:

(A) Monitoring relevant performance characteristics and detecting changes in performance;
(B) Identifying sources of performance changes between validation and real-world environment over time; and
(C) Assessing the results from the performance testing on safety and effectiveness;

(ii) Procedures for communicating the device's current performance to the users.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

FDA's granting of your De Novo request also included the review and authorization of your Predetermined Change Control Plan (PCCP) titled "Predetermined Change Control Plan (PCCP) for PCWP Analysis Software Rev 1". Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the authorized PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the software device system for estimation of cardiac pressuresthey intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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) for devices or postmarketing safety reporting (21 CFR 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Monica Okon at Monica.Okon@fda.hhs.gov.

Sincerely,

HETAL B. ODOBASIC -S

Hetal Odobasic
Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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