September 26, 2025

Caretaker Medical
Jeff Pompeo
CEO
941 Glenwood Station Ln
Suit 301
Charlottesville, Virginia 22901

Re: K251275
Trade/Device Name: VitalStream ART Connect; VitalStream-Hemo
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II
Product Code: DXG
Dated: August 29, 2025
Received: August 29, 2025

Dear Jeff Pompeo:

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,

Stephen C. Browning -S

LCDR Stephen Browning
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251275

Please provide the device trade name(s).

Trade Names: VitalStream ART Connect; VitalStream-Hemo

Common Name: ART Dock

Please provide your Indications for Use below.

The VitalStream ART Connect (aka VitalStream-Hemo) provides calibrated cardiac output/stroke volume (CO) and derived parameters, including cardiac index (CI), stroke volume (SV), stroke volume index (SVI), systemic vascular resistance (SVR), systemic vascular resistance index (SVRI), mean arterial pressure (MAP), heart rate (HR), and pulse pressure variation (PPV) in adult patients to the existing Caretaker Remote Display App And Caretaker Software Library (K181196) via Pulse Decomposition Analysis ("PDA") (K211588, K163255, K151499). The device is intended for use on adult patients by physicians or other properly trained medical personnel in a hospital or other appropriate clinical setting.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1) **Preparation Date**: Aug 29, 2025

2) **Submitted by**:
Caretaker Medical, Inc
941 Glenwood Station Ln, Suite 301
Charlottesville, Virginia 2290
User Fee Organization Number 397095
Owner/Operator #: 10054848

3) **Contact Person/Prepared by**:
Jeff Pompeo
President & CEO
CareTaker Medical
941 Glenwood Station Ln, Suite 301
Charlottesville, Virginia 2290
Phone: 434-409-1945
Email: Jeff@caretakermedical.net

4) **Device Identification:**

Trade Name: VitalStream ART Connect
VitalStream-Hemo
Common Name: ART Dock
Classification: 21 CFR 870.1435
Product Code: DXG
Device Class: II

5) **Predicate Device:** Argos Monitor by Retia Medical (K181372)

6) **Device Description:** The VitalStream ART Connect is an adapter to accept the analog output channel of commercial invasive arterial catheter blood pressure monitors. An on-board analog to digital converter provides access to a digitized version of the raw invasive blood pressure signal and presents it to the Caretaker Platform (K211588) to provide the same parameters that were previously obtained through a filtered pneumatic signal (Caretaker Advanced Hemodynamic Parameters, K213699).

7) **Intended Use:** The VitalStream ART Connect (aka VitalStream-Hemo) provides calibrated cardiac output/stroke volume (CO) and derived parameters, including cardiac index (CI), stroke volume (SV), stroke volume index (SVI), systemic vascular resistance (SVR), systemic vascular resistance index (SVRI), mean arterial pressure (MAP), heart rate (HR), and pulse pressure variation (PPV) in adult patients to the existing Caretaker Remote Display App And Caretaker Software Library (K181196) via Pulse Decomposition Analysis ("PDA")(K211588, K163255, K151499). The device is intended for use on adult patients by physicians or other properly trained medical personnel in a hospital or other appropriate clinical setting.

8) Comparison to Predicate:

Both the VitalStream ART Connect and the Argos Monitor are capable of processing the analog output channel of commercial invasive arterial catheter blood pressure monitors to provide Cardiac Output and derived parameters, including cardiac index (CI), stroke volume (SV), stroke volume index (SVI), systemic vascular resistance (SVR), systemic vascular resistance index (SVRI), mean arterial pressure (MAP), heart rate (HR), and pulse pressure variation (PPV). The main difference is in the method of measurement. While the Argos Monitor uses a novel signal processing technique to determine the parameters of the Windkessel model of circulation, the ART Dock uses Pulse Decomposition Analysis (PDA) and modified Wesseling method.

9) Clinical Testing

a. Objective and Patient Population

The goal of the study was to assess the capability of the VitalStream ART Connect (ART Dock) to provide cardiac output (CO) and stroke volume (SV) measures at an accuracy matching that of the predicate device. To this end the CO and SV measures provided by the ART Dock were assessed against those obtained from the Gold Standard, thermodilution (TD) as well as, for one set of patients, the semi-real-time output of continuous cardiac output (CCO) catheters.

The specific performance guideline was to provide CO measurements with errors below 30% in measurement compared to the TD/CCO reference. In addition, aspects of the study addressed the following performance questions:

- Response time to cardiac output changes.
- Tracking accuracy in a patient population with valvular disease.
- Tracking accuracy in a patient population with arrhythmias.

Baseline characteristics of patients in both TD comparison studies

Study Site	**Site 1 25 patients**	**Site 2 37 patients**
Characteristic	**Mean (SD) or N (%)**	**Mean (SD) or N (%)**
Overall age – mean (std)	64.4 (9.7)	
Age range	30 - 84	
Age – mean (std) – yr.	63.7 (12.7)	66.2 (12.6)
Body Mass Index – mean (std. dev.) – kg/m^2	31.1 (6.7)	29.1 (6.3)
Male Sex – no. (%)	17 (68)	23 (62)
Hypertension – no. (%)	13 (54)	26 (70)
Diabetes Mellitus – no. (%)	12 (47)	6 (16)
Indications (%)		
Aortic Insufficiency, Stable Angina, or known Coronary Artery Disease,	15 (61)	13 (35)
Valvular Disease	11 (44)	33 (89.2)
Other Indications	5 (20)	4 (10.8)
CABG	6 (34)	13 (35.1)

b. Conclusions:

The Vitalstream ART Connect is substantially equivalent to the Argos Monitor in terms of providing the hemodynamic parameters cardiac output and stroke volume based on arterial pulse signals obtained from an intravascular radial arterial blood pressure signal, although the ART Dock uses a different methodology (PDA/modified Wesseling) to obtain these hemodynamic parameters.

Performance Characteristic	***VitalStream ART Connect***	***Argos Monitor [1] (Predicate device)***
Demonstrated CO range	2 – 14 l/min	2 – 8.0
mean (accuracy) ± SD (precision)	**0.22 ± 0.74 l/min**	**-0.20 ± 1.14 l/min**
MAE	**25.1**	**50.8**
Clinical study cohort size	62 subjects (40 m/22 f) 164 comparative measurements	58 (48 m/ 10 f) 572 comparative measurements
Clinical study cohort age means (SD)	64.6 ± 9.9	70 ± 10

- The VitalStream ART Connect response to cardiac output changes compares to that of the predicate device, which according to the manual has two options (20-second or 5-minute averaging) and is significantly faster than the current invasive CCO Gold Standard.
- Performance of the VitalStream ART Connect's cardiac output measurements did not degrade in the population subsets of patients with valvular issues and patients with arrhythmias.