August 13, 2021

Caretaker Medical
Jeff Pompeo
President & CEO
941 Glenwood Station Ln #301
Charlottesville, Virginia 22901

Re: K211588
Trade/Device Name: Caretaker Platform
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DRG
Dated: May 12, 2021
Received: May 24, 2021

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 (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 located 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.

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 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 systems (QS) regulation (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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211588

Device Name
Caretaker Platform

Indications for Use *(Describe)*
The Caretaker Platform is intended for non-invasive, continuous or spot-check measurement of hemodynamic parameters. Parameters can be reported to an integrated screen and optionally to Remote Data Display Systems (RDDS) and/or the Caretaker Remote Monitor App via standard wireless or wired data transmission protocols. The device is intended for use by clinicians or other properly trained personnel on adult patients at rest.

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.

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510(k) Summary of Safety and Effectiveness

1) **Preparation Date**: 12 May 2021

2) **Submitted by**:

Caretaker Medical, LLC
941 Glenwood Station Ln; Suite 301
Charlottesville, Virginia 22901
User Fee Organization Number 397095
Owner/Operator #: 10054848

3) **Contact Person/Prepared by**:

Jeff Pompeo
President & CEO
Phone: 434-409-1945
Email: Jeff@caretakermedical.net

4) **Device Identification:**

Trade Name:	Caretaker Physiological Monitor System
Common Name:	Caretaker Platform
Alternate Marketing Names:	Vitalstream
	CT5

Classification: 21 CFR 870.1130,
Product Code: DXN –System, Measurement, Blood-Pressure, Non-Invasive
Device Class: II

5) **Predicate Devices:** Caretaker4 Physiological Monitor (K151499, K163255), Caretaker Monitor (K181196)

6) **Device Description:** The Caretaker Platform is a hemodynamic monitoring system that non-invasively measures various parameters via a finger cuff based on the scientific method of Pulse Decomposition Analysis ("PDA"). The Caretaker physical device is calibrated using any manual or AAMI 81060 compliant blood pressure device or is automatically calibrated using its self-calibration mode. The Caretaker Remote Monitor consists of an App that runs on Remote Data Display Systems (RDDS) and a set of APIs to for additional command and control functions developed on Android, Windows, or Linux systems.

7) **Intended Use:** The Caretaker Platform is intended for non-invasive, continuous or spot-check measurement of hemodynamic parameters. Parameters can be reported to an integrated screen and optionally to Remote Data Display Systems (RDDS) and/or the Caretaker Remote Monitor App via standard wireless or wired data transmission protocols. The device is intended for use by clinicians or other properly trained personnel on adult patients at rest.

8) **Comparison to Predicates:**

Summary of methodology

Comparison bench-testing was performed to compare the current device to the predicate Caretaker4 since both use the Pulse Decomposition Analysis (PDA) method for the tracking of hemodynamic parameters. The comparison tests focused on the the algorithmic performance

because the physiological sensing and electronic processing hardware that constitutes both device's front ends are the same.

The bench tests are performed in the Caretaker Analyzer GUI (CA GUI), which is a custom-designed environment for the development and testing of the algorithms that analyze and process incoming arterial pulse signal data to produce vital signs.

The CA GUI can perform comprehensive testing across platforms and versions, i.e. the performance of PDA algorithms, both in firmware and desktop software versions for both CT4 and DUT CT5, can be assessed by selecting appropriate menu items.

Provision of continuous non-invasive hemodynamic parameters

Both devices measure blood pressure within AAMI SP-10 guidelines. Both devices require calibration and are intended for use on adult patients administered by trained medical staff. Both systems are identical with regard to electronic circuitry, pneumatic layout and components and algorithmic pulse analysis. The new model CT5 has a touch screen interface which the predicate device does not have. Both systems operate at a coupling pressure significantly lower than normal diastole with a lower risk of occluding blood flow to the monitored digit, making the technology safer

Provision of spot-check non-invasive hemodynamic parameters

Both the predicate Caretaker and the present system use an oscillometric sweep to obtain point-in-time measurements within AAMI guidelines. The predicate device used this sweep solely for the purpose of self-calibration before switching to its relative change monitoring mode. In addition to the self-calibration, the present CT5 can also be set to periodically wake and use the same sweep to get multiple point-in-time measurement at isochronal periods set by the end user.

Provision of use of software

Both the predicate Caretaker and the present system use the same Caretaker Remote Monitor App software and APIs. The new CT5 device includes additional feature keys to set different configuration options for various hemodynamic parameters that were always on by default in the previous device. The feature keys are unique to each physical device serial number and are set at time of manufacture to create different models (all using the same hardware).

9) **Conclusions:**

Provision of non-invasive hemodynamic parameters

The Caretaker Platform is substantially equivalent to the predicate Caretaker device in regard to providing continuous, non-invasive hemodynamic monitoring. The spot-check mode of the present system is substantially equivalent to the self-calibration mode of the predicate.

Provision of use of software

The Caretaker Platform is substantially equivalent to the Caretaker Remote Monitor App and APIs in that the same software is used with the addition of the feature keys described above.