March 30, 2022

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

Re: K213699
Trade/Device Name: Caretaker Advanced Hemodynamic Parameters
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN, DRG
Dated: March 1, 2022
Received: March 2, 2022

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K213699

Device Name

Caretaker Advanced Hemodynamic Parameters

Indications for Use *(Describe)*

The Caretaker Advanced Hemodynamic Parameters provides calibrated cardiac output/stroke volume (CO/SV), left ventricular ejection time (LVET), and heart rate variability (HRV) in adult patients to the existing Caretaker Remote Display App And Caretaker Software Library (K181196) via Pulse Decomposition Analysis ("PDA")(K211588, K163255, K151499). To provide CO/SV measurements, the Caretaker platform is to be calibrated with a thermodilution measurement, or other accurate reference determination of cardiac output, to ensure accuracy. The device is intended for use by physicians or other properly trained medical personnel in a hospital or other appropriate clinical setting.

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

510(k) Summary of Safety and Effectiveness

1) **Preparation Date**: 29 Mar 2022

2) **Submitted by**:

Caretaker Medical, LLC
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
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Phone: 434-409-1945
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4) **Device Identification:**

Trade Name:	Caretaker Advanced Hemodynamic Parameters
Common Name:	Caretaker Advanced Hemodynamic Parameters
Product Code(s):	DXN –System, Measurement, Blood-Pressure, Non-Invasive
	DRG - Transmitters and Receivers, Physiological signal, Radiofrequency
Regulation Number(s):	21 CFR 870.1130
	21 CFR 870.2910
Device Class:	II

5) **Predicate Devices:** Nexfin_HD (for cardiac output/stroke volume, K072049), Finapres Portapres model 2 (for left ventricular ejection time, K023338), and ANSWatch (for heart rate variability measures, K123130).

6) **Device Description:** The Caretaker Advanced Hemodynamic Parameters is a firmware upgrade that runs on the Caretaker platform to provide additional hemodynamic measures to the Caretaker Remote Display App And Caretaker Software Library, K181196, and CareTaker Physiological Monitor, (K211588, K163255, K151499). These parameters are not intended to predict or detect cardiovascular mortality or any other condition, disease, and/or patient outcome.

7) **Intended Use:** The Caretaker Advanced Hemodynamic Parameters provides calibrated cardiac output/stroke volume (CO/SV), left ventricular ejection time (LVET), and heart rate variability (HRV) in adult patients to the existing Caretaker Remote Display App And Caretaker Software Library (K181196) via Pulse Decomposition Analysis ("PDA")(K211588, K163255, K151499). To provide CO/SV measurements, the Caretaker platform is to be calibrated with a thermodilution measurement, or other accurate reference determination of cardiac output, to ensure

accuracy. The device is intended for use by physicians or other properly trained medical personnel in a hospital or other appropriate clinical setting.

8) **Comparison to Predicates:**

- **Cardiac Output / Stroke Volume**

The patient groups represent challenged cardiac physiologies that necessitated the monitoring of cardiac output among other vital signs. Common to all groups is a high incidence of hypertension, 76%, as well as diabetes, 26%. Less than 16%, across all cohorts, have a normal BMI<25. The CTM PDA model currently does not use patient demographic data because internally obtained correlations between such data and hemodynamic parameters such as blood pressure, CO etc. are weak.

CTM's approach to calculating CO incorporates refined approaches to modeling efforts that others have pursued. The Windkessel, Area-Under-the-Curve, approach that was originally proposed by Warner 1 is based on two concepts: A) mass is conserved, meaning the volume of blood entering a vessel is equal to the volume leaving, B) compliance is part of the model since during systole, as pressure inside the vessel is increasing, the vessel expands and absorbs some of the blood that would otherwise pass through it. During diastole, as the pressure inside the vessel drops, the vessel contracts and the additional blood that was stored during systole is expelled. After dividing the pulse contour into systolic and diastolic regions, flow equations for both regions can be established that relate stroke volume to the ratio of systolic to diastolic pulse areas and the end-systolic pressure while aortic resistance is incorporated via a proportionality constant.

The Caretaker Physiological Monitor System is substantially equivalent to the NexFin_HD in terms of providing the hemodynamic parameters cardiac output and stroke volume based on arterial pulse signals obtained from a finger cuff, preferably with calibration via thermodilution, although Caretaker uses a slightly different methodology (PDA/modified Wesseling) to obtain these hemodynamic parameters. Caretaker has clinically validated evidence attesting equivalent performance to that of the predicate device and followed quality management system rigor to comply with IEC 60601 safety standards.

- **Left Ventricular Ejection Time (LVET)**

Baseline demographic information is presented below

Characteristic	**Mean (SD) or N (%)**
Age – mean (std. dev.) – yr.	66.8 (9.8)
Body Mass Index – mean (std. dev.) – kg/m^2	31.4 (7.3)
Male Sex – no. (%)	27 (57.5)
Tobacco Use – no. (%)	31 (66.0)
Hypertension – no. (%)	40 (85.1)
Diabetes Mellitus – no. (%)	22 (46.8)
Indication for Cardiac Catheterization – no. (%)	
Acute Coronary Syndrome, Stable Angina, or known Coronary	28 (59.6)

Artery Disease	
Valvular Disease	12 (25.5)
Other Indications	7 (14.9)
Vascular Access Site – no. (%)	
Radial Artery	26 (55.3)
Femoral Artery	21 (44.7)

Primary indications for cardiac catheterization procedures mostly consisted of coronary evaluation (37/47, 78%). Other primary indications included hemodynamic assessment for a suspected severe aortic stenosis. The radial artery was more commonly used for a vascular access (27/47, 57%) compared to the femoral artery. Of the study participants, 21% underwent percutaneous coronary intervention.

LVET was obtained from central aortic BP tracings by measuring the time interval between the initiating point of upstroke of the aortic pressure wave form and the dichrotic notch according to established guidelines.

The Caretaker Physiological Monitor System is substantially equivalent to the Portapres model 2 in terms of providing the LVET hemodynamic parameter based on arterial pulse signals obtained from a finger cuff. Both the predicate device and the Caretaker use pulse analysis of the arterial pressure pulse to determine LVET. Caretaker has clinically validated evidence attesting equivalent performance to that of the predicate device and followed quality management system rigor to comply with IEC 60601 safety standards.

- **Heart Rate Variability**

  Overall subject demographics were as follows: age (mean: 50.9 y (standard deviation: 16.8)), sex (34 m/26 f), height (67.1 inch (4.43)), weight (179 lbs. (36.5 BMI (28.2 (5.41)).

  The protocol of the interventions utilized hand in ice-bath immersions, ice bag on forehead, light valsalva maneuvers, ball gripping and leg raises. In addition there were extended period of supine relaxation.

  The Caretaker Physiological Monitor System is substantially equivalent to the ANSWatch in terms of providing heart rate variability measures derived from a peripheral mechanical arterial pulse sensor. The Caretaker has clinically validated evidence attesting performance equivalent to or better than the predicate device.

9) **Conclusions:**

- **Cardiac Output / Stroke Volume** The CareTaker Monitor is substantially equivalent to the NexFin_HD.

- **Left Ventricular Ejection Time (LVET)** The CareTaker Monitor is substantially equivalent to the Portapres model 2.

- **Heart Rate Variability** The CareTaker Monitor is substantially equivalent to the ANSWatch.