DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 18, 2016

Caretaker Medical, LLC
Jeff Pompeo
President & CEO
3042 Berkmar Drive Suite A
Charlottesville, Virginia 22901-1455

Re: K151499
Trade/Device Name: Caretaker Wireless Vital Signs Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: February 16, 2016
Received: February 17, 2016

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. 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.

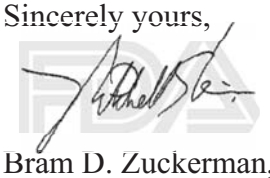
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K151499

Device Name

CareTaker Wireless Vital Signs Monitor

Indications for Use *(Describe)*

CareTaker is intended to noninvasively and continuously measure a patient's blood pressure ("BP") and heart rate ("HR"), which are derived from the pulse pressure waveform using the scientific method of Pulse Decomposition Analysis ("PDA") for use on adult patients at rest. CareTaker is calibrated using a manual sphygmomanometer. All parameters derived by CareTaker are reported to a remote display monitor via standard radio transmission. CareTaker does not provide any physiological alarm functions. The device is intended for use by clinicians or other properly trained medical personnel in a hospital or other appropriate clinical settings.

Type of Use *(Select one or both, as applicable)*

X 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**: June 3, 2014

2) **Submitted by**:

CareTaker Medical, LLC
3042 Berkmar Drive, Suite A
Charlottesville, Virginia 22901-1455
User Fee Organization Number 397095
Owner/Operator #: TBD

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

Jeff Pompeo
President & CEO
CareTaker Medical
3042 Berkmar Drive, Suite A
Charlottesville, Virginia 22901-1455
Phone: 434-409-1945
Email: Jeff@caretakermedical.net

4) Device Identification:

Trade Name: CareTaker Wireless Vital Signs Monitor
Common Name: CareTaker Continuous Non-Invasive Blood Pressure Monitor
Classification: 21 CFR 870.1130,
Product Code: DXN –System, Measurement, Blood-Pressure, Non-Invasive
Device Class: II

5) **Predicate Device:** Nexfin HD (K072049)

6) **Device Description:** _CareTaker is a cardiovascular monitoring device that non-invasively measures continuous blood pressure and heart rate via a finger cuff based on the scientific method of Pulse Decomposition Analysis ("PDA")

7) Intended Use: CareTaker is intended to noninvasively and continuously measure a patient's blood pressure ("BP") and heart rate ("HR"), which are derived from the pulse pressure waveform using the scientific method of Pulse Decomposition Analysis ("PDA") for use on adult patients at rest. CareTaker is calibrated using a manual sphygmomanometer. All parameters derived by CareTaker are reported to a remote display monitor via standard radio transmission. CareTaker does not provide any physiological alarm functions. The

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

8) Comparison to Predicate:

Both the CareTaker and the NextFin predicate device are continuous non-invasive blood pressure and heart rate monitors that derive these physiological parameters from the arterial pulse collected by a finger cuff.

The devices are characterized by the following common features and differences:

- Both devices measure blood pressure within AAMI SP-10 (AAMI/ANSI/ISO 81060) guidelines.
- Both devices require calibration and are intended for use on adult patients in clinical settings administered by trained medical staff.
- Both devices obtain the required arterial pulse pressure signal from a digit. However, the Nexfin utilizes the Penaz principle, which requires that the arterial pressure be matched by the dynamic coupling pressure throughout the cardiac cycle, resulting in variable pressure and poor user comfort as well as occlusion of venous blood return. The CareTaker system, on the other hand, utilizes the Pulse Decomposition Algorithm pulse analysis approach to track blood pressure by monitoring the time evolution of temporal and amplitudinal pulse parameters. This approach requires only a low, constant coupling pressure well below diastole, without any occlusion.
- Since the CareTaker system operates at a significantly lower coupling pressure with a lower risk of occluding blood flow to the monitored digit, the CareTaker technology is safer.
- The Predicate's Penaz principle monitors the digit's blood volume using plethysmography, which requires electronic circuitry in the finger cuff for driving optical sources, such as light-emitting diodes, and for deriving electrical signals from the optical interrogation, using photo diodes. In contrast, the CareTaker system requires no electrical components to be part of the finger cuff.

9) Testing: The CareTaker has been tested in a clinical study to compare with an arterial catheter in recording blood pressure. The results are compliant with the ISO 81060-2 standard. Additionally, testing in accordance with the IEC 60601-1 and IEC 60601-1-2 standards has verified that the CareTaker is safe and electromagnetically compatible, similar to the predicate device.

10) Conclusion: The CareTaker device is substantially equivalent to the NexFin_HD in terms of capturing Blood Pressure and Heart Rate parameters from a finger cuff after manual calibration, although CareTaker uses a different methodology (PDA) to interpret and display the actual HR and BP parameters. CareTaker has clinically validated evidence attesting adherence to AAMI SP-10 (AAMI/ANSI/ISO 81060) standards and followed quality management system rigor to comply with IEC 60601 safety standards.