



April 21, 2017

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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

Re: K163255

Trade/Device Name: CareTaker4 Physiological Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 15, 2017
Received: March 16, 2017

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,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K163255

Device Name
CareTaker4 Physiological Monitor

Indications for Use (Describe)

CareTaker is intended to noninvasively and continuously measure a patient's blood pressure ("BP"), heart rate ("HR"), and respiration rate ("RSP"), 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 method or any AAMI 81060 compliant BP device, or is automatically calibrated using its self-calibration mode. All parameters derived by CareTaker are reported to an integrated LCD screen and optionally to a remote display monitor (RDDS) via standard radio transmission protocols. The device is intended for use by clinicians or other properly trained medical personnel and does not provide any physiological alarm functions.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

510(k) Summary of Safety and Effectiveness

- 1) **Preparation Date:** November 9, 2016

- 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: CareTaker4 Physiological Monitor
Classification: 21 CFR 870.1130,
Product Code: DXN –System, Measurement, Blood-Pressure, Non-Invasive
Device Class: II

- 5) **Predicate Devices:** CareTaker (K151499), Nexfin HD (K072049), HealthPatch MD (K152139)

- 6) **Device Description:** CareTaker is a cardiovascular monitoring device that non-invasively measures continuous blood pressure, heart rate and respiration rate via a finger cuff based on the scientific method of Pulse Decomposition Analysis (“PDA”). CareTaker is calibrated using any manual or AAMI 81060 compliant blood pressure device or is automatically calibrated using its self-calibration mode.

- 7) **Intended Use:** CareTaker is intended to noninvasively and continuously measure a patient’s blood pressure (“BP”), heart rate (“HR”) and respiration rate (“RSP”), 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 method or any AAMI 81060 compliant BP device, or is automatically calibrated using its self-calibration mode. All parameters derived by CareTaker are reported to an integrated LCD screen and optionally to a remote display monitor (“RDDS”) via standard radio transmission protocols. The device is intended for use by clinicians or other properly trained medical personnel and does not provide any physiological alarm functions.

8) **Comparison to Predicates:**

Provision of continuous non-invasive blood pressure and heart rate

Both the predicate CareTaker and the present CareTaker system use the Pulse Decomposition Analysis method for the tracking of blood pressure. Both devices measure blood pressure within AAMI SP-10 guidelines. Both devices require calibration and are intended for use on adult patients in clinical settings administered by trained medical staff. Both systems are identical with regard to electronic circuitry, pneumatic layout and components and algorithmic pulse analysis. While the CareTaker4 has an on-board display, the predicate CareTaker does not. While the CareTaker4 is capable of self-calibration, the predicate CareTaker is not. While the CareTaker4 is capable of determining respiration rates, the predicate CareTaker is not. 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 is safer.

Provision of calibrated blood pressure readings

The CareTaker system and the predicate Nexfin_HD device provide calibrated blood pressure readings. While the Nexfin_HD uses the Penaz/Physiocal method to obtain blood pressure calibration, the CareTaker uses the principle of oscillometry. Both devices measure blood pressure within AAMI SP-10 guidelines. Both devices obtain the required arterial pulse pressure signal from a digit. However, because they use different technologies for the determination of blood pressure, their coupling to the monitored digit is very different. Since the CareTaker system operates at a significantly lower coupling pressure with a lower risk of occluding blood flow to the monitored digit, the technology is safer. The ability of the CareTaker system to operate with lower, constant coupling pressure also has significant consequences regarding portability and versatility of the technology compared to that of the predicate Nexfin device.

Provision of respiration rate readings

With regard to respiration rate detection, both the CareTaker4 and the predicate HealthPatch MD analyze a pulsatile, heartbeat-related signal. In the case of the CareTaker4 it is the derivative arterial pressure pulse, in the case of the respiration detection predicate device it is an EKG signal. In both systems signal amplitude and inter-beat interval-related changes are used to detect and determine the respiration rate.

9) **Conclusions:**

Provision of continuous non-invasive blood pressure and heart rate

The CareTaker4 device is substantially equivalent to the predicate CareTaker device in regard to providing continuous blood pressure and heart rate readings.

Provision of calibrated blood pressure readings

The CareTaker4 device is substantially equivalent to the NexFin_HD in terms of providing calibrated blood pressure readings from a finger cuff, although CareTaker4 uses a different methodology (PDA). Like the Nexfin_HD, CareTaker4 has clinically validated evidence attesting adherence to SP10 standards and followed quality management system rigor to comply with IEC 60601 safety standards.

Provision of respiration rate readings

The CareTaker4 device is substantially equivalent to the HealthPatch MD in terms of providing a respiration rate derived from a pulse sensor, although CareTaker4 uses a differentiated arterial pulse signal while the predicate device uses an EKG signal. The CareTaker4 has clinically validated evidence attesting performance equivalent to or better than the predicate device.