October 3, 2018

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

Re: K181196
Trade/Device Name: Caretaker Remote Display App and Caretaker Software Library
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DRG
Dated: September 5, 2018
Received: September 5, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Shawn W. Forrest -A

Digitally signed by Shawn W. Forrest -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300403341, cn=Shawn W. Forrest -A
Date: 2018.10.03 22:18:36 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181196

Device Name
Caretaker Remote Display App and Caretaker Software Library

Indications for Use *(Describe)*
The Caretaker Remote Display App and Caretaker Software Library are indicated for use when remote display and/or forwarding of securely transmitted wireless data from the Caretaker Physiological Monitor device (K163255) is required. The Remote Display App and the Software Library provides bi-directional data transfer capabilities with the Caretaker Physiological Monitor device (K163255). To facilitate communications between the Caretaker Physiological Monitor device and other FDA Cleared patient monitors and Remote Data Displays (RDDS), the Caretaker Software Library provides a well-defined interface for 3rd party data integrations.

In addition to providing data display and forwarding, the Remote Display App can operate as an MDDS for 3rd party wireless medical devices. The alerts in the subject device are only to be used for historical review and are not intended for time-critical intervention.

The Software Library is intended only for use by licensed partners of the company, and the Caretaker Remote Display App is intended for use by clinicians or other properly trained medical personnel. Both the Remote Display App and Software Library are for prescriptive use only.

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**: Aug 31, 2018

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
941 Glenwood Station Ln, Suite 301
Charlottesville, Virginia 22901-1455
Phone: 434-409-1945
Email: Jeff@caretakermedical.net

4) **Device Identification:**

Trade Name: CareTaker Remote Display App and CareTaker Software Library
Common Name: CareTaker App
Classification: 21 CFR 870.1130,
Product Codes: DXN –System, Measurement, Blood-Pressure, Non-Invasive
DRG - Transmitters And Receivers, Physiological Signal, Radiofrequency
Device Class: II

5) **Predicate Devices:** VIOS Monitoring System, K150992
Airstrip ONE Web Client, K160862

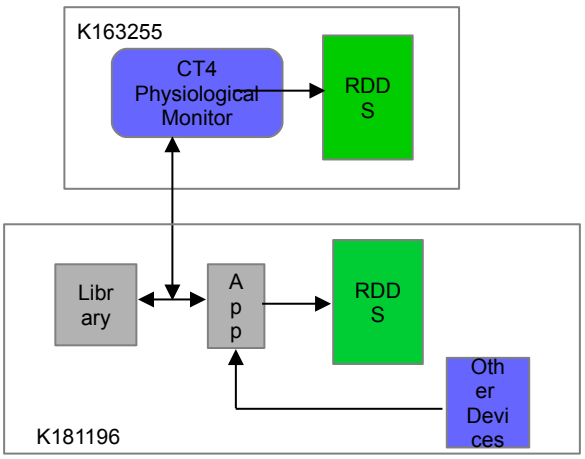
6) **Device Description:** CareTaker Medical's App ("CareTaker Remote Display App") is a software App that runs on Commercial, Off the Shelf (CoTS) hardware to provide additional controls and features to the CareTaker4 Physiological Monitor, K163255, as well as an interface to other devices.

The App is a software platform that displays and stores physiological parameters and waveforms from patient monitoring medical devices. CareTaker Remote Display App can also forward this data to third party systems, including Electronic Medical Records systems.

The integrated CareTaker Software library provides new control and configuration functions to a connected CareTaker4 Physiological Monitor. This library can also be used by 3rd parties to develop their own Apps that are capable of controlling a CareTaker4 as well. The library does not and cannot control any other medical devices or systems it is connected with.

CareTaker Remote Display App can function without the CareTaker Software Library, in which case it is the same as the RDDS in K163255.

The relationships between the various items as well as between K163255 and K181196 are shown conceptually below.



7) **Intended Use:**

The Caretaker Remote Display App and Caretaker Software Library are indicated for use when remote display and/or forwarding of securely transmitted wireless data from the Caretaker Physiological Monitor device (K163255) is required. The Remote Display App and the Software Library provides bi-directional data transfer capabilities with the Caretaker Physiological Monitor device (K163255). To facilitate communications between the Caretaker Physiological Monitor device and other FDA Cleared patient monitors and Remote Data Displays (RDDS), the Caretaker Software Library provides a well-defined interface for 3rd party data integrations.

In addition to providing data display and forwarding, the Remote Display App can operate as an MDDS for 3rd party wireless medical devices. The alerts in the subject device are only to be used for historical review and are not intended for time-critical intervention.

The Software Library is intended only for use by licensed partners of the company, and the Caretaker Remote Display App is intended for use by clinicians or other properly trained medical personnel. Both the Remote Display App and Software Library are for prescriptive use only.

8) **Comparison to Predicate:**

Feature	VIOS Monitoring System	Airstrip ONE Web Client	CareTaker App
Indications for Use	The Vios Monitoring System (VMS) is intended for use by medically qualified personnel for physiological and vital signs monitoring of adult (18+) patients in healthcare facilities. It is indicated for use in monitoring of ECG, heart rate, pulse rate, functional oxygen saturation of arterial hemoglobin, and axillary	Information is generated by other medical devices and patient information system, and not by this device. This device captures this information from these other systems and displays it for clinicians. This device is intended to be used by clinicians for the following purposes:	The Caretaker Remote Display App and Caretaker Software Library are indicated for use when remote display and/or forwarding of securely transmitted wireless data from the Caretaker Physiological Monitor device (K163255) is required. The Remote Display

	temperature. VMS allows for the input of non-invasive blood pressure and can display data from peripheral devices. VMS can generate alerts when rate-based cardiac arrhythmias are detected and when physiological vital signs fall outside of selected parameters.	• To view the near real-time waveforms remotely • To remotely review other standard or critical near real-time patient data from the monitored system • To provide a request for remote consultation regarding a patient's waveform or other data This device software can display the following physiologic data captured by other medical devices: • ECG Waveform • Heart Rate Monitored • Respiratory Rate • Oxygen Saturation • Intracranial Pressure • Central Venous Pressure • Pulmonary Capillary Wedge Pressure • Cardiac Index • Cardiac Output • Cerebral Perfusion Pressure • Systolic Blood Pressure Invasive • Mean Arterial Pressure Invasive • Diastolic Blood Pressure Invasive • Systolic Blood Pressure Cuff • Mean Arterial Pressure Cuff • Diastolic Blood Pressure Cuff Contraindications This device is intended for use by clinicians when they cannot be at the hospital. This device is intended for use by clinicians as a diagnostic aid, and not as a replacement for direct viewing of any of the monitoring devices from which it obtains its data.	App and the Software Library provides bi-directional data transfer capabilities with the Caretaker Physiological Monitor device (K163255). To facilitate communications between the Caretaker Physiological Monitor device and other FDA Cleared patient monitors and Remote Data Displays (RDDS), the Caretaker Software Library provides a well-defined interface for 3rd party data integrations. In addition to providing data display and forwarding, the Remote Display App can operate as an MDDS for 3rd party wireless medical devices. The alerts in the subject device are only to be used for historical review and are not intended for time-critical intervention. The Software Library is intended only for use by licensed partners of the company, and the Caretaker Remote Display App is intended for use by clinicians or other properly trained medical personnel. Both the Remote Display App and Software Library are for prescriptive use only.
Device Regulatory Classification	- 21 CFR 870.2300; Cardiac monitor (including cardiotachometer and rate alarm) - 21 CFR 890.2910 Transmitters And Receivers, Physiological Signal, Radiofrequency (Class II, Cardiovascular) - 21 CFR 880.2910 Clinical Electronic Thermometer (Class	21 CFR 870.2300; Cardiac monitor (including cardiotachometer and rate alarm)	- 21 CFR 870.1130; System, Measurement, Blood-Pressure, Non-Invasive - 21 CFR 890.2910 Transmitters And Receivers, Physiological Signal, Radiofrequency (Class II, Cardiovascular)

	II exempt, General Hospital)		
Product Code	DRT, DRG, FLL	MSX	DXN, DRG
Device Class	II	II	II
510(k)	K150992	K160862	K181196
Other Technologies Used	Standard computers, network, and WIFI	Standard computers, network, and WIFI	Standard computers, tablets, cell phones, network, WIFI, and Bluetooth
Where Used	Anywhere clinicians remotely consult on patients.	Used by clinicians when they cannot be at the hospital.	Anywhere clinicians consult on patients (local or remote).
Wireless	Yes, handheld display devices	Yes, multiple devices and technologies	Yes, handheld display devices
Ability to view near real-time data	Yes	Yes	Yes
Alerts	Software generated	No	Software generated
Synopsis of Functionality	Store, route and display patient data, generate and display alarms	Remotely view near real-time waveforms and patient data	Store and display patient data and optionally route to EMR, provide alarms set by operator

9) **Conclusions:**

The safety and effectiveness of the CareTaker Remote Display App have been confirmed through non-clinical testing and conformance to vital signs monitoring, usability, and risk assessment. The App was tested by connecting to a CareTaker4 Physiological Monitor Device using the CareTaker Software Library and to both a SpO2 monitor and a temperature patch using industry standard BLE Protocols to receive data. Data forwarding was tested using both WiFi and USB protocols to an external RDDS.

Storing, Displaying, and Forwarding Patient Data
The Caretaker Remote Display App and CareTaker Software Library are safe to use as they are substantially equivalent to the predicate devices. There are no significant differences in technologies, operating principles, or intended use.

Alarm Functions
The Caretaker Remote Display App and CareTaker Software Library are safe to use as the visual and audio alarms only indicate when a received parameter exceeds a limit set by the operator. No processing of physiological data is done by the App or library. The alarms latch to ensure they are viewed by the operator, but are not intended for time-critical intervention. The alarms are retained for review of historical data.

Controlling the CareTaker4 Physiological Monitor
The Caretaker Remote Display App and CareTaker Software Library are safe to use as the control functions are the same as are available on the previously cleared CareTaker4 Physiological Monitor Device, K163255, and do not alter the safety or efficacy of the CareTaker4 Physiological Monitor itself. The App provides a more convenient method to control the device rather than using the 1-button interface on the device.