FEB 14 2014

510(k) SUMMARY

Verizon Wireless
Converged Health Management Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Verizon Wireless
One Verizon Way
Basking Ridge, NJ 07920
Phone: 202-515-2454
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Contact Person: Lolita Forbes, Assistant General Counsel – Mobile Health

Date Prepared: December 27, 2013

Name of Device and Name/Address of Sponsor

Verizon Wireless Converged Health Management Device

Verizon Wireless
One Verizon Way
Basking Ridge, NJ 07920

Common or Usual Name: Telemedicine System

Classification Name: Radiofrequency Physiological Signal Transmitter and Receiver

Predicate Devices:

The Verizon Wireless Converged Health Management Device is a modification to K122458 Verizon Wireless Converged Health Management Device.

Intended Use

The CHM Device is a remote monitoring software solution intended to collect and store biometric data from physiological measurement devices intended for use in the home. The CHM Device also allows for the automated transmission of the biometric data to a remote secure server via an existing mobile telecommunications and/or internet infrastructure.

The stored biometric data is accessible by clinicians for analysis and intervention. Patients can also review the stored biometric data and receive educational and motivational content from clinicians.

The CHM Device can be used as a standalone device or in conjunction with supported patient monitoring devices, such as a glucometer, weight scale, pulse oximeter, and blood pressure monitor.

The CHM Device is not intended for use in surgical rooms, intensive care units, intermediate or step-down units or emergency vehicles. It is not interpretive, nor is it intended for diagnosis or as a replacement for the oversight of healthcare professionals. It does not provide real-time or emergency monitoring.

Technological Characteristics

The CHM is a software platform for the collection and display of biometric data, primarily from externally supported patient monitoring devices, both to the patient and to the clinician. The CHM Device may also be used as a standalone device. The CHM Device uses existing Internet and telecommunications architecture (cell phones and computers) for the automated transmission of medical data to a remote secure server from where it can be viewed remotely by clinicians and patients for the purposes of storage and basic analysis. The CHM Device also provides educational and motivational functionalities allowing the clinician to send tasks, recommendations, surveys, and educational and motivational messages to patients.

The Verizon Wireless Converged Health Management Device may be used in conjunction with the following externally supported patient monitoring devices:

- Ideal Life Inc., Blood Pressure Cuff (K060504)
- Ideal Life Inc., Glucose Monitor Model GMM0001 (K080283)
- Ideal Life Inc. SpO2 Pulse Oximeter (K070371)

- Ideal Life Inc., Weight Scale (Class I, 510(k) Exempt)
- Ideal Life Inc. Communication Gateway Ideal Life Pod ILP (K080538)
- Telecare Inc., Blood Glucose Monitoring System (K110571)
- Genesis Health Technologies, Blood Glucose Monitoring System (K121224)

Performance Data

As part of its software verification and validation activities, regression and usability testing was performed to ensure that the changes to the software have not introduced new faults and that a change to one part of the software does not affect other parts of the software. Additional verification and verification activities were performed to ensure that the biometric data was transferred accurately from the Telcare and Genesis Health glucometers server infrastructure into the CHM platform. All verification and validation activities, as required by the risk analysis, were performed and the results demonstrated that the predetermined acceptance criteria were met.

Substantial Equivalence

The Verizon Wireless Converged Health Management Device has the same intended Use and indications for use and its predicate, Verizon Wireless Converged Health Management Device (K122458). It also has identical technological characteristics as the predicate device. Software verification and validation testing demonstrate that the Verizon Wireless Converged Health Management Device performs as intended and that the differences between the Verizon Wireless Converged Health Management Device and its predicate do not raise new questions of safety or effectivenesss.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

February 14, 2014

Cellco Partnership D/b/a Verizon Wireless
Ms. Lolita Forbes
Assistance General Counsel
One Verizon Way
Basking Ridge, NJ 07920 US

Re: K134004
Trade/Device Name: Verizon Wireless Converged Health Management Device
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: December 27, 2013
Received: December 27, 2013

Dear Ms. Lolita Forbes:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR 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.htmfor 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 Small Manufacturers, International and Consumer Assistance 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,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Verizon Wireless Converged Health Management System

Indications for Use:

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Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801 Subpart D) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2014.02.14 11:51:21 -05'00'