

**510(k) Summary**

**Verizon Wireless  
Converged Health Management Device (K122458)**

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

Cellco Partnership d/b/a Verizon Wireless  
One Verizon Way  
Basking Ridge, NJ 07920  
Phone: (202) 515-2454  
Facsimile: (202) 289-6781

JUL 30 2013

Contact Person: Lolita Forbes, Assistant General Counsel – Mobile Health  
[lolita.forbes@verizon.com](mailto:lolita.forbes@verizon.com)

Date Prepared: July 3, 2013

**Name of Device and Name/Address of Sponsor**

Verizon Wireless Converged Health Management Device

Cellco Partnership d/b/a Verizon Wireless  
One Verizon Way  
Basking Ridge, NJ 07920

**Common or Usual Name:** Telemedicine System

**Classification Name:**

Radiofrequency Physiological Signal Transmitter and Receiver (21 CFR 870.2910; DRG)

**Predicate Devices:**

Alcatel-Lucent Telehealth Manager (K092635)  
Vignet Telehealth Monitoring System (K113446)

**Intended Use / Indications for 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 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 Device 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 (cellphones 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 SpO2 Pulse Oximeter (K070371)
- Ideal Life Weight Scale (Class I, 510(k)-exempt)
- Ideal Life Communication Gateway Ideal Life Pod ILP (K080538)

### **Performance Data**

The Verizon Converged Health Management Device is a software application. Software verification and validation testing, including usability validation, was performed successfully, demonstrating that the CHM Device performs appropriately per defined specifications, meets all input requirements, fulfills the device's intended use, and correctly incorporates all required safety mitigations.

### **Substantial Equivalence**

The CHM Device has the same intended use and similar indications for use as its predicate devices. The CHM Device also has similar technological characteristics as its predicate devices. Software verification and validation testing demonstrate that the CHM Device performs as intended and that the differences between the CHM Device and its predicate devices do not raise new questions of safety or effectiveness.



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

July 30, 2013

Cello Partnership D/B/A Verizon Wireless  
C/O Ms. Lolita Forbes  
Assistant General Counsel - Mobile Health  
1300 I St NW, Suite 400 W  
Washington, DC 20005

Re: K122458  
Trade/Device Name: Verizon Wireless Converged Health Management System  
Regulation Number: 21 CFR 870.2910  
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver  
Regulatory Class: Class II  
Product Code: DRG  
Dated: 06/04/2013  
Received: 06/04/2013

Dear Ms. 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 contact 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>. 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 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

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K122458

Device Name: Verizon Wireless Converged Health Management (CHM) Device

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Prescription Use  X   
(Part 21 CFR 801 Subpart D)

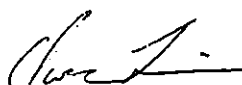
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Digitally signed by Owen  
P. Farris -S  
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