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

June 2, 2017

VitalConnect, Inc.
Kevin Potgieter
Senior Manager, Regulatory Affairs
224 Airport Parkway, Suite 300
San Jose, California 95110

Re: K170973
Trade/Device Name: VitalWatch Software User Interface
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: March 31, 2017
Received: April 3, 2017

Dear Kevin Potgieter:

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,

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)*
K170973

Device Name
VitalWatch Software User Interface

Indications for Use *(Describe)*
VitalWatch is a software user interface intended for use by healthcare professionals to display physiological data collected by the VitalConnect Platform wireless remote monitoring system in home and healthcare settings. VitalWatch is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.

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 – VitalWatch™ Software User Interface

510(k) Owner's Name, Address, and Telephone Number
VitalConnect, Inc.
224 Airport Parkway, Suite 300
San Jose, CA 95110
(408) 963-4600

Contact Person
Kevin Potgieter, MS, RAC
Senior Manager, Regulatory Affairs
Office: (408) 963-4603
Cell: (424) 263-8484
Fax: (408) 963-2828
Email: kpotgieter@vitalconnect.com

510(k) Number: K170973

Date Prepared: 31 May 2017

Trade Name of Device: VitalWatch Software User Interface

Common or Usual Name: User Interface for Wireless Remote Monitoring System

Classification Name:
21 CFR 870.2910 – Transmitters and Receivers, Physiological Signal, Radiofrequency

Product Code: DRG

Predicate Device(s)
VitalConnect Platform by VitalConnect, Inc. (K152139)

Intended Use

VitalWatch is a software user interface intended for use by healthcare professionals to display physiological data collected by the VitalConnect wireless remote monitoring system in home and healthcare settings. VitalWatch is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.

Device Description
VitalWatch is a software user interface designed to be manufacturer-installed and user-executed on a validated Relay device, which serves as a graphical user interface that displays physiological data provided by the VitalConnect wireless remote monitoring system.

Technological Characteristics
This 510(k) does not involve any changes to the technological characteristics of the VitalConnect Platform.

Performance Data
Software verification and validation testing was conducted and documentation is provided in accordance with the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Applying Human Factors and Usability Engineering to Medical Devices, and Postmarket Management of Cybersecurity in Medical Devices. VitalWatch software has a "Moderate" Level of Concern.

Substantial Equivalence
The VitalConnect Platform, modified to include the VitalWatch software user interface, has the same intended use and technological characteristics as the predicate device and is therefore substantially equivalent to the predicate device.

Conclusions
The VitalConnect Platform is substantially equivalent to the predicate device. The modifications described in this 510(k) do not raise different questions of safety and effectiveness.

Summary Substantial Equivalence Table

Topic	**Predicate Device** ***K152139***	**Modified Device** ***VitalWatch***
Classification	Class II	Class II
Classification Name	Transmitters and Receivers, Physiological Signal, Radiofrequency	Transmitters and Receivers, Physiological Signal, Radiofrequency
Product Code	DRG	DRG
Trade Name	VitalConnect Platform®, HealthPatch® MD, VitalPatch®	VitalConnect Platform®, HealthPatch® MD, VitalPatch®, VitalWatch ™
Physiological Data Monitored	Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall)	Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall)
Principles of Operation	Display of data from validated Relay device using third-party developed Graphical User Interface and optional transmission of data to Secure Server.	Display of data from validated Relay device using third-party developed Graphical User Interface, or VitalWatch, and optional transmission of data to Secure Server.