November 2, 2017

Vital Connect, Inc.
Kevin Potgieter
Senior Manager, Regulatory Affairs
900 E. Hamilton Avenue
Suite 500
Campbell, California 95008

Re: K163453
Trade/Device Name: VitalPatch® VitalConnect Platform
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, DSI, MHX
Dated: October 12, 2017
Received: October 13, 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 (DICE) 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 (DICE) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K163453

Device Name
VitalPatch® VitalConnect Platform

Indications for Use *(Describe)*
The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include 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). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.

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.

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510(k) SUMMARY – Modification to VitalPatch®

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
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510(k) Number: K163453

Date Prepared: 30 October 2017

Trade Name of Device: VitalPatch® VitalConnect Platform

Common or Usual Name: Wearable Biosensor

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
The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings.

Indications for Use
The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include 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). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.

Device Description
VitalPatch is a wearable biosensor which may be used as part of the VitalConnect Platform. The device is a disposable, battery-powered, adhesive patch containing sensors used to gather patients' physiological data, which are transmitted wirelessly. The modification proposed in this 510(k) increases the wear duration for the VitalPatch wearable biosensor from 96 hours to 120 hours.

Technological Characteristics
This 510(k) does not involve any changes to the technological characteristics of the VitalPatch wearable biosensor.

Performance Data
The following device performance tests were performed on the VitalPatch wearable biosensor during the early design and development phase:

Test Description	**Standard/Guidance Referenced**
Electrical Safety Testing	IEC 60601-1, 3.1 Ed.
Electromagnetic Compatibility Testing	IEC 60601-1-2, 4th Ed.
Battery Performance Testing	N/A – internal performance testing
Skin Adherence/Wear Duration	N/A – internal performance testing
Wear Performance (Sensor Functionality)	N/A – internal performance testing
Wireless Coexistence	FDA Radio Frequency Wireless Technology in Medical Devices

The following device performance tests were performed on the VitalPatch wearable biosensor during the commercialization phase, in support of this 510(k) submission for the extension of wear duration from 96 to 120 hours:

Test Description	**Standard/Guidance Referenced**
Firmware Verification and Validation	FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Substantial Equivalence
VitalPatch with the 120-hour wear duration has the same intended use, indications for use, and technological characteristics as the predicate device. Thus, VitalPatch is substantially equivalent to the predicate device.

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

Summary of Substantial Equivalence Table

Topic	**Predicate Device** ***K152139***	**Modified Device** ***K163453***
Classification	Class II 21 CFR 870.2910	Class II 21 CFR 870.2910
Classification Name	Transmitters and Receivers, Physiological Signal, Radiofrequency	Transmitters and Receivers, Physiological Signal, Radiofrequency
Product Code	DRG	DRG
Trade Name	VitalPatch®	VitalPatch®
Patch Configuration	Disposable adhesive patch containing integrated disposable sensor module	Disposable adhesive patch containing integrated disposable sensor module
Shelf Life	9 months	9 months
Vital Signs 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)
Wear Duration	96 hours	120 hours
Principles of Operation	Adhesive patches affixed to user's torso allowing for continuous monitoring of wearer's physiological data. Wireless transmission and storage of data via Relay devices and optional Secure Server.	Adhesive patches affixed to user's torso allowing for continuous monitoring of wearer's physiological data. Wireless transmission and storage of data via Relay devices and optional Secure Server.