March 7, 2019

VitalConnect, Inc.
% Robert Packard
President
Medical Device Academy, Inc.
345 Lincoln Hill Road
Shrewsbury, Vermont 05738

Re: K183078
Trade/Device Name: VitalConnect Platform, VitalPatch Biosensor
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, DSI, MHX
Dated: November 5, 2018
Received: November 5, 2018

Dear Robert Packard:

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 and Part 809; 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,

Arielle Drummond -S

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)*
K183078

Device Name
VitalConnect Platform, VitalPatch Biosensor

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, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Biosensor 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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

VitalConnect, Inc.
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Tel: +1.408.963.4600
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Contact Person: Cynthia Merrell, VP QA&RA
Date Prepared: March 6, 2019

II. DEVICE

Name of Device:	VitalConnect Platform, VitalPatch Biosensor
Classification Name:	Cardiovascular Monitoring Devices
Regulation:	21 CFR §870.2910, 21 CFR 870.1025
Regulatory Class:	Class II
Product Classification Code:	DRG, DSI, MHX

III. PREDICATE DEVICE

Predicate Manufacturer:	Vital Connect, Inc.
Predicate Trade Name:	VitalConnect Platform, VitalPatch Biosensor
Predicate 510(k):	K163453

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

VitalPatch is a wearable biosensor designed to measure a patient's vital signs, including 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). VitalPatch was most recently cleared in K163453.

The following modifications are proposed for the VitalPatch wearable biosensors:

- An ambient temperature sensor is added to the original VitalPatch, which was most recently cleared in K163453, to measure ambient temperature. The measured ambient temperature along with the measured skin temperature cleared in K163453 are used to calculate the body temperature.
- An updated IFU for VitalPatch has been created to reflect the temperature sensor changes.

All other vital signs, including 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) cleared in K163453 remain the same.

V. 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, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Biosensor 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The intended use and technological features of the proposed Vital Connect Platform do not substantially differ from the legally marketed predicate device. The Vital Connect Platform and the predicate device have substantially equivalent intended uses and methods of operation.

Table 1 Comparison of Indications for Use (change is identified in **bold** font)

Predicate (K163453)	**Subject Device**
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, body temperature, 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.	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, **body temperature,** 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.

Table 2 Size Comparison of the adhesive patch

Dimension	Predicate (K163453)	Subject Device
Length	115 mm	120 mm
Width	35.6 mm	40.6 mm
Height	7.5 mm	9.4 mm

Table 3 Component Comparison of the Predicate and Proposed Devices

Component	Predicate (K163453)	Proposed Device
ECG electrodes	Allow the recording of a single-lead bipolar ECG at a sampling rate of 125 Hz	Identical
Skin Thermistor	Mounted on the patch. Designed to monitor skin temperatures when the patch is attached to the skin.	Identical
Ambient Thermistor	N/A – only in subject device	Designed to monitor ambient temperature to more accurately calculate body temperature using the skin temperature input.
Flexible Assembly	Provides a connection between the ECG electrodes, thermistors and patch electronics. The flexible circuit is sealed within the patch.	Equivalent except the addition of the ambient thermistor
Firmware	Rev. 1.0.1.13 to support functions listed in Table 4 for Predicate (K163453)	Version 3.1.0.1 of firmware adds: • Support for VitalPatch 3 hardware • Sense ambient temperature • Body temperature derivation • Ability to blink the LED • 30° bed-angle posture calibration • 120-hour patch-life timer (based on K163453 clearance) • Maintenance improvements

Table 4 – Device Performance Characteristics Comparison

Performance Characteristic	Predicate (K163453)	Proposed Device
Wireless Transmission	Bluetooth Low Energy (BT4.1) technology	Identical
Data encryption	Advanced Encryption Standard-CCM mode	Identical

Radio Frequency	2.4GHz ISM band FCC Part 15 Complied	Identical
ECG Dynamic Range	The Sensor electrodes make contact with the skin to measure the differential voltage generated from the heart. The resulting analog ECG waveform is digitized so that the data can be streamed to a display or recording device. Range: -10mV to +10mV	Identical
Heart Rate (stationary and ambulatory)	Heart rate is measured and calculated in Beats Per Minute (BPM) both for stationary and ambulatory use. Range: 30 - 200 BPM	Identical
Respiratory Rate	From a combination of ECG and tri-axial accelerometer sensor signals, the Vital Connect Sensor can accurately measure the respiratory rate of the person, irrespective of whether the person is stationary or ambulatory. Range: 10-30 breaths per minute	Identical
Skin Temperature	Using a thermistor sensor on the Patch, which is in close proximity to the skin, the Vital Connect Sensor accurately measures the temperature of the skin, reporting the temperature in degrees Centigrade. A known quantity of current generated by the sensor is converted to a voltage that is accurately matched to skin temperature. Range: 15°C - 50 °C (61°F - 113°F)	Identical
Ambient Temperature	N/A – Subject Device Only	Using an additional thermistor sensor on the Patch, which is away from the skin, the VitalConnect Biosensor accurately measures patch ambient temperature, reporting the temperature in degrees Centigrade. A known quantity of current generated by the sensor is converted to a voltage that is accurately matched to the ambient temperature. Range: 15°C - 50 °C (61°F - 113°F)
Body Temperature	N/A – Subject Device Only	A calculated value as a function of the skin and ambient temperatures. Range: 32°C - 42°C

Fall Detection	Using a tri-axial accelerometer and digital signal processing techniques, the Vital Connect Sensor detects falls while minimizing false notifications. Range: Fall or No Fall	Identical
Step Count	The Vital Connect Sensor also uses the tri-axial accelerometer to compute step count. As the person walks, the Vital Connect Sensor is capable of distinguishing steps from other movements. The detected steps are accumulated to provide an accurate step count. Range: 0 - 65535 steps	Identical
Posture Detection	Using the built-in tri-axial accelerometer, the Vital Connect Sensor can determine the posture of the person and provide wireless real-time updates to a central server. Postures detected include lying down, upright, walking, running and leaning.	Identical
R-R Interval	The R-R interval is the measurement of the interval from the R wave peak of one QRS complex to the next R-wave peak on the electrocardiogram. The device has enhanced QRS performance during motion.	Identical
Heart Rate Variability	HRV quantifies the variation in the beat-to-beat interval time series obtained from the ECG waveform. Using advanced signal processing algorithms, the Sensor detects each QRS peak with high temporal accuracy. Measurement of the R wave to R wave (RR) interval allows short and long-term variability analysis to determine analytics such as mean, median, standard deviation, frequency content, etc.	Identical
Low Power Mode	When patch is off the body, to conserve battery power, the processor goes into a low power mode, resulting in reduced current draw.	Identical

VII. PERFORMANCE DATA

Verification and validation activities established the safety and performance characteristics of the proposed device with respect to the predicate. The following performance data have been provided in support of the substantial equivalence determination:

Sterilization & Shelf-life Testing

The Vital Connect Platform is provided non-sterile, and therefore sterilization data is not provided. Accelerated aging data was provided to support a shelf-life of 9 months as previously cleared.

Biocompatibility Testing

Biocompatibility testing, previously conducted, included in-vitro cytotoxicity, irritation and sensitization, according to the recommendations of ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the VitalPatch. The device complies with the IEC 60601-1, IEC 60601-1-11, IEC 60601-2-25, and the IEC 60601-2-47 standards for safety. The device also complies with the IEC 60601-1-2 standard for EMC, IEC/TS 62657-2 and FCC CRF47 Part 15 Subpart C standards for wireless communication.

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The software for this device is determined as a "moderate" level of concern because a failure or latent flaw could lead to a minor injury to the patient through incorrect information or through the action of the care provider.

Benchtop & Simulated Use Testing

Shipping validation and transit testing and was performed to demonstrate that changes to VitalPatch did not negatively affect the safety and efficacy when compared to the predicate device. Paired readings, using VitalPatch and hand-held oral thermometers simultaneously, were analyzed to verify accuracy when compared to the hand-held oral thermometers.

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Clinical Studies

Clinical testing was not required to demonstrate the safety and effectiveness of the VitalPatch. Instead, substantial equivalence is based upon benchtop performance testing.

VIII. CONCLUSIONS

The subject device is substantially equivalent in design and intended use to the predicate device. Any differences between the subject device and the predicate device have no significant influence on safety or effectiveness as established through performance testing. Therefore, the subject device raises no new issues of safety or effectiveness from the predicate device.