February 6, 2020

VitalConnect, Inc.
Cynthia Merrell
Vice-President, QA & RA
224 Airport Parkway, Suite 300
San Jose, California 95110

Re: K192757
Trade/Device Name: VitalPatch 5D Biosensor - single, VitalPatch 7D Biosensor - single, VitalPatch 5D Biosensor – bag of 20, VitalPatch 7D Biosensor – bag of 20
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: September 30, 2019
Received: September 30, 2019

Dear Cynthia Merrell:

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); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih
Assistant Director (Acting)
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K192757

Device Name
VitalConnect 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 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. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. 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.

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510(k) SUMMARY

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

I. SUBMITTER

VitalConnect, Inc.
Address 224 Airport Parkway, Suite 300
San Jose, CA, 95110, USA
Tel: +1.408.963.4600
Fax: +1.408.963.2828

Contact Person: Cynthia Merrell, VP QA&RA
Date Prepared: Feb 05, 2020

II. DEVICE

Name of Device:	VitalPatch
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:	VitalPatch® Biosensor
Predicate 510(k):	K190916

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, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). VitalPatch was most recently cleared in K190916.

There are three device modifications included in this 510(k) pre-submission:

1. removal of the pacemaker contraindication from the VitalPatch instructions for use,
2. heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate are not intended for patients with pacemakers.
3. the patch setup procedure interface was modified to select whether the patient has a pacemaker; the response inhibits as appropriate the functions not intended for patients with pacemaker. If pacemaker is indicated as present, the device will not transmit or

store heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate.

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 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. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers.

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

Predicate (K190916)	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. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. The device is not intended for use on critical care patients.

Table 2 Size Comparison of the adhesive patch

Dimension	Predicate (K190916)	Subject Device
Length	120 mm	120 mm
Width	40.6 mm	40.6 mm
Height	9.4 mm	9.4 mm

Table 3 Component Comparison of the Predicate and Subject Devices

Component	Predicate (K190916)	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	Designed to monitor ambient temperature to more accurately calculate body temperature using the skin temperature input.	Identical
Flexible Assembly	Provides a connection between the ECG electrodes, thermistors and patch electronics. The flexible circuit is sealed within the patch.	Identical
Firmware	Version 3.2.1.0 of firmware fixes a bug and allows configuration for 120-hour patch life timer or 168-hour patch-life timer.	The firmware in subject device fixes bugs, is modified to attenuate distortions due to pacemaker artifacts. If pacemaker is indicated as present, the device will not transmit or store heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate..

Table 4 – Device Performance Characteristics Comparison

Performance Characteristic	Predicate (K190916)	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 when pacemaker is indicated as absent; ECG is not available for patients with pacemakers
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 when pacemaker is indicated as absent; Heart rate is not available for patients with pacemakers
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 when pacemaker is indicated as absent; Respiratory rate is not available for patients with pacemakers
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	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)	Identical
Body Temperature	A calculated value as a function of the skin and ambient temperatures. Range: 32°C - 42°C	Identical
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 when pacemaker is indicated as absent; R-R interval is not available for patients with pacemakers
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 when pacemaker is indicated as absent; HRV is not available for patients with pacemakers
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

Pacemaker spikes	• EMI interference on the pacemaker was not tested due to pacemaker contraindication. • VitalPatch device does not detect or display pacemaker spikes. • Effect of pacemaker spikes on ECG signal was not tested due to pacemaker contraindication. • Effect of pacemaker spikes on heart rate was not tested due to pacemaker contraindication. • Effect of pacemaker spikes on respiratory rate was not tested due to pacemaker contraindication.	• Testing is performed to show that EMI interference on the pacemaker by the VitalPatch Biosensor is within allowable limits for pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 • VitalPatch device does not detect or display pacemaker spikes. • Display of ECG signal is not available for patients with pacemakers. • Heart Rate values (including heart rate variability and R-R interval) is not available for patients with pacemakers. • Respiratory Rate is not available for patients with pacemakers..

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)

Testing was performed to show that EMI interference on the pacemaker by the VitalPatch Biosensor is within allowable limits for pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000.

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

The following testing was performed to assess the performance of the subject device in the presence of pacemaker:

- Performance testing of heart rate in non-pacemaker subjects after bug fixes.
  - *Summary:* Testing shows the Heart Rate after modifications satisfies the clinical acceptance criteria in non-pacemaker subjects.
- Pacemaker Status Check Test
  - *Summary*: Testing shows that if pacemaker is indicated as present, the device will not transmit or store heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate. Moreover, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are correctly displayed/transmitted/stored when pacemaker is indicated as absent.
- Battery current draw testing of subject device
  - *Summary:* When tested under the same operating scenario, the predicate and subject device draw same amount of current. Hence, the battery current consumption between the predicate and subject device is substantially equivalent.

Animal Study

Animal performance testing was not required for this device.

Clinical Studies

Clinical testing was performed in non-pacemaker human subjects to demonstrate substantial equivalence in heart rate and respiratory rate of the subject device.

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 performance testing. Therefore, the subject device raises no new issues of safety or effectiveness from the predicate device.