DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 6, 2015

Vital Connect, Inc.
Bonnie Wu
Sr. Regulatory Manager
900 E. Hamilton Avenue, Suite 500
Campbell, California 95008

Re: K152139
Trade/Device Name: Vital Connect Platform, Healthpatch MD, VitalPatch
Regulation Number: 21 CFR
Regulation Name:
Regulatory Class: Class II
Product Code: DRG, DSI, MHX
Dated: November 2, 2015
Received: November 4, 2015

Dear Bonnie Wu:

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.

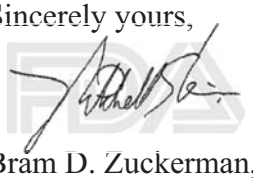
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 yours,



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)*
K152139

Device Name

Vital Connect Platform

Indications for Use *(Describe)*

The Vital Connect 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 Vital Connect Sensor for storage and analysis. The Vital Connect 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 Vital Connect 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.

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6.0 510(k) Summary

In accordance with the provisions of the Safe Medical Device Act of 1990, Vital Connect, Inc. is providing a summary of Safety and Effectiveness information regarding the Vital Connect Platform.

6.1 Company Identification

Vital Connect, Inc.

900 E. Hamilton Ave. Suite 500

Campbell, CA 95008

Registration Number: 3010830833

6.2 Contact Person

Bonnie Wu

Sr. Manager, Regulatory Affairs

Telephone: 408-963-4620

Fax: 408-963-2828

Email: bwu@vitalconnect.com

6.3 Preparation Date

July 31, 2015

6.4 Identification of Product and Classification

Device Trade Name: Vital Connect Platform, HealthPatch® MD, VitalPatch™

Common Name: Wireless Remote Monitoring System

Classification Name: Transmitters and Receivers, Physiological Signal, Radiofrequency

Classification Panel: Cardiovascular

CRF Section: 870.2910, 870.1025

Device Class: II

Product Code: DRG, DSI, MHX

6.5 Predicate Device

Manufacturer: Vital Connect, Inc.

Model: Vital Connect Platform

510(k) Number: K141167

6.6 Device Description

The Vital Connect Platform is a wireless data collection system that monitors physiological data and consists of the following sub-systems:

- Vital Connect Sensor (includes Adhesive Patch and Sensor Module)
  a) Adhesive Patch

  The Adhesive Patch is designed as a disposable self-adhesive interface to the body.

  b) Sensor Module

  The Sensor Module performs processing functions related to capture of physiologic data and also performs bi-directional communication with the Relay Software Library.

- Relay Software Library
  The Relay Software Library manages communication with the Vital Connect Sensor. The Relay Software Library also manages the communication with the Secure Server when the Secure Server is deployed. The Relay Software Library is installed on a relay device.

The Vital Connect Platform offers an optional sub-system:

- Secure Server
  The Secure Server manages the upload, processing and storage of sensor data, as well as real-time configuration and notification communications with the Relay Software Library.

The Vital Connect 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 Vital Connect Sensor for storage and analysis. The Vital Connect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The Vital Connect Sensor continuously gathers physiological data from the person being monitored and then transmits encrypted data via bi-directional communication to the relay device when in range of the relay. The encrypted wireless data provided by the Sensor may be downloaded from the relay device for storage, or integrated into a Third-Party Relay Application via the APIs of the Relay Software Library. In addition, the wireless data may be transferred to the Vital Connect Secure Server where they are stored for analysis with the deployment of the server.

During normal operation, data are collected on the Vital Connect Sensor and transmitted to the Relay immediately. A continuous connection is needed between the Sensor and the Relay in order to facilitate continuous data transmission. The continuous wireless transmission of the data occurs with a delay or latency of seconds between continuous data collection and transmission. Data can be stored and downloaded from the Relay. Data can continue to be transferred to the Vital Connect Server with a server connection. If an interruption occurs

between the Sensor and the Relay, data will be stored on the Sensor for several hours until the connection is re-established.

6.7 Indication for Use

The Vital Connect 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 Vital Connect Sensor for storage and analysis. The Vital Connect 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 Vital Connect 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.

6.8 Technology Characteristics

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.

6.9 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.

6.9.1 Summary of 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*.

6.9.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Vital Connect Sensor. The device complies with the IEC 60601-1, IEC 60601-1-11, IEC 60601-1-6, IEC 60601-2-25, and IEC 60601-2-47 standards for safety, the IEC 60601-1-2 standard for EMC, IEC/TS 62657-2 and FCC CRF47 Part 15 Subpart C standards for wireless communication.

6.9.3 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.

6.9.4 Bench Testing

In vitro bench testing, including shelf life, packaging integrity, operation and storage conditions, water resistance, static load, compression, and drop test were conducted to verify the modified device met all acceptance criteria and performed similarly to the predicate device.

6.9.5 Animal and Clinical Testing

Prior clinical testing was performed to support the clearance of the predicate device and is still relevant to the proposed device. The safety and effectiveness of the device associated with the product changes are demonstrated through performance testing. Thus, animal and clinical studies were not deemed necessary.

6.10 Conclusion

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