K141167

JUL 29 2014

510(k) Summary

The summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter:	Vital Connect Inc. 900 East Hamilton Avenue Suite 500 Campbell, CA 95008
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Date Prepared:	June 03, 2014
Trade name:	VitalConnect Platform (consisting of VitalConnect Sensor, Relay Software Library and Secure Server Software Library)
Classification:	Class II
Classification:	***Classifications presented as part of the VitalConnect Platform cleared 510(k) submission (K132447):*** 21 CFR 870.2910, Product Code: DRG • Transmitters and Receivers, Physiological Signal, Radiofrequency 21 CFR 870.1025, Product Code: DSI • Arrhythmia detection and alarm (including ST-segment measurement and alarm) ***New classification for home use indication:*** 21 CFR 870.1025, Product Code: MHX • Monitor, physiological, patient (with arrhythmia detection or alarm)
Predicate Device:	***Predicate devices presented as part of the VitalConnect Platform cleared 510(k) submission (K132447):*** • CareFusion, Wireless Monitoring System, 510(k) #: K110809 • Preventice, BodyGuardian System, 510(k) #: K121197 • Corventis, Mobile Patient Management System, 510(k) #: K083287

	New predicate device for home use indication: • Hidalgo Ltd, Equivalent™ Vital Signs Physiological Monitor EQo2, K113054
Classification Panel:	Cardiology
Device Description:	The VitalConnect Platform is a wireless data collection system that monitors physiological data and consists of the following sub systems: • VitalConnect Sensor (includes adhesive Patch and Sensor Module) • Relay Software Library • Server Software Library VitalConnect Platform sub-system includes: • **VitalConnect Sensor** a) Adhesive Patch The Patch is designed as a disposable self-adhesive interface to the body. b) Sensor Module Residing within the patch, the sensor module performs processing functions related to capture of physiological data and also performs bi-directional communication with the relay device. • **VitalConnect Relay Software Library** The Relay Software Library manages bi-directional communication between the Sensor Module and the Server Software Library and is installed on a relay device. • **VitalConnect Secure Server Software Library** The Server Software Library is installed on a central server, manages the upload, processing and storage of sensor data, as well as configuration of and notifications from the VitalConnect Platform. The VitalConnect Sensor continuously gathers physiological data from the person being monitored and then transmits encrypted data via a bi-directional relay to the central server. During normal operation, continuous wireless transmission occurs with a delay or latency of seconds between continuous data collection and transmission. However, for continuous transmission of data to a healthcare professional, a continuous connection is needed between the module, the relay, and the server. Data can be stored on the VitalConnect Sensor for several hours and then transferred once connectivity is reestablished.

	The VitalConnect Sensor is a battery-operated adhesive patch with integrated sensors and wireless transceiver module, worn on the torso to record 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).
Physical Description:	VitalConnect Sensor consisting of Patch and the Sensor Module dimensions are: • Patch: approximately 111 mm long x 47mm wide x 6 mm high (without the release liner) • Sensor Module: approximately 21 mm long x 12 mm wide x 4 mm high
Indication 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 includes 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 is transmitted wirelessly to a central location where it is stored for analysis. The Vital Connect Platform can be configured by Authorized Persons to notify healthcare professionals when physiological data falls 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 is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients.

Comparison of Technological Characteristics:	Technological review and comparison to the predicate device, Hidalgo Ltd, Equivalent ™ Vital Signs Physiological Monitor EQo2, K113054, has been performed through product testing presented as part of the cleared 510(k) submission K132447. The VitalConnect Platform and the predicate device (Hidalgo Ltd, Equivalent™ Vital Signs Physiological Monitor EQo2, K113054) contain small ambulatory monitoring sensors that measure ECG, heart rate, respiration rate, activity, body orientation, body/skin temperature. Both transmit their data to a remote computer server that allows healthcare professionals to access and review the data. There are no fundamental differences between their technological characteristics for home setting environment. Therefore, we claim that VitalConnect Platform is substantially equivalent to Hidalgo Ltd, Equivalent ™ Vital Signs Physiological Monitor EQo2 (K113054) in this regard.
Non-Clinical Testing:	Non-clinical bench testing was presented as part of the VitalConnect Platform cleared 510(k) submission (K132447). This testing is applicable to the indication submitted here in, including testing of: • Electrocardiograph (ECG) • Heart rate • Heart rate variability (R-R interval) • Respiration rate • Body impedance • Activity (including step count), • Posture (body position relative to gravity including fall) • Bluetooth verification • Notification • Measurement accuracy • Communication, data transmission and storage • Reliability • Electromagnetic compatibility • Electrical safety testing • Co-existence testing • Software verification and validation testing • Biocompatibility verification and testing
Clinical Testing:	An IRB-approved "Long-term Field Study for Home Use" was conducted by Vital Connect with the VitalConnect Platform from September 2013 to March 2014, to assess the long-term use of the VitalConnect Platform in a home setting. The assessment includes the usability of the VitalConnect Platform in a home setting, including interaction with the module, patch, and relay.

	In addition, the assessment includes the long-term wearability of a series of patches on the same participants. Results indicate successful use of the VitalConnect Platform over a 50-day home use study on 76 participants.
Biocompatibility:	The initial 510k submission, K132447, included biocompatibility data for the hydrocolloid adhesive. In this submission, a medical grade silicone adhesive has been added as a separate option for the patch. The silicone adhesive has been subjected to the following safety evaluation: • In Vitro Cytotoxicity • MEM Elution • Primary Skin Irritation • Guinea Pig Sensitization
Conclusion:	The performance results for the VitalConnect Platform included non-clinical and clinical testing already submitted as part of K132447, and the biocompatibility testing data of silicone adhesive and clinical study in a home setting are provided in this 510(k) demonstrate that VitalConnect Platform is safe and effective for its intended use, including use in the home environment. Based on the intended use and product performance results, VitalConnect Platform has been shown to be substantially equivalent for home use to the currently marketed predicate device, Hidalgo Ltd, Equivalent ™ Vital Signs Physiological Monitor EQo2, K113054.

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

July 29, 2014

Vital Connect Inc.
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Re: K141167
Trade/Device Name: Vitalconnect platform (consisting of vitalconnect sensor, relay software library and secure server software library)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG, DSI, MHX
Dated: June 3, 2014
Received: June 4, 2014

Dear Sam Mostafavi,

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), 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K141167

Device Name: VitalConnect Platform

Indication 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 includes 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 is transmitted wirelessly to a central location where it is stored for analysis. The Vital Connect Platform can be configured by Authorized Persons to notify healthcare professionals when physiological data falls 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 is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram Zuckerman
