April 20, 2020

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

Re: K193343/S001
Trade/Device Name: Vista Solution
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: December 3, 2019
Received: December 3, 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,

for

Jennifer Shih
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K193343

Device Name
Vista Solution

Indications for Use *(Describe)*
Vista Solution 2.1 is a software user interface intended for use by healthcare professionals to display physiological data collected by the VitalConnect Platform wireless remote monitoring system in home and healthcare settings. Vista Solution is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.

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) substantial equivalence information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

VitalConnect, Inc.
Address 224 Airport Parkway, Suite 300
City San Jose, CA, 95110 USA
Tel: 1-408-963-4600
Fax: 1-408-963-2828

Contact Person: Cynthia Merrell
Date Prepared: March 19, 2020

II. DEVICE

Name of Device:	Vista Solution
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulation:	21 CFR § 870.2910
Regulatory Class:	Class II
Product Classification Code:	DRG

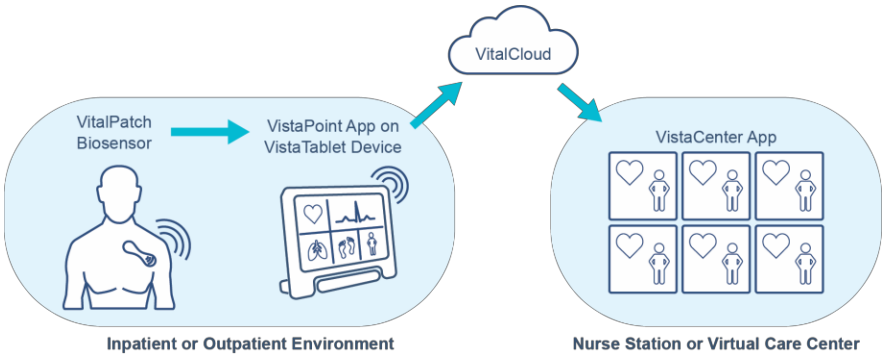
III. PREDICATE DEVICE

Predicate Manufacturer:	VitalConnect, Inc.
Predicate Trade Name:	VitalWatch Software User Interface
Predicate 510(k):	K170973

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The VitalConnect Platform, Vista Solution is a wireless remote monitoring system consisting of the VitalPatch biosensor (K190916) and the VistaCenter and VistaPoint software (formally branded as VitalWatch in K170973). This submission is a catch-up 510(k) for changes made to the software since K170973 was cleared. The principles of operation, mechanism of action, and proposed environment of use are unchanged from the predicate device (K170973).



VistaCenter Application
A web application that interfaces with the VCI Cloud and displays live and historical data for multiple patients and supports download of historical data for multiple patients. The application also supports the user entry of criteria for triggering notifications based on data values and for displaying notifications generated from such criteria.

VistaPoint Application
The VistaTablet 2.0 App is a stand-alone Android Application which is delivered pre- installed on an off-the-shelf tablet and the combination called VistaTablet 2.0. It incorporates within a single distributable application the functionality of the Relay App, and VistaPoint. The VistaTablet runs a single application that is a combination of Relay App, Configuration App, VistaPoint, and a product wrapper to make it run like a native application.

The user interface on VistaTablet is substantially equivalent to the previously commercialized VistaTablet 1.0 product with the following major additions:

- Support for third-party devices for collecting additional vital signs – SpO2, Blood Pressure, and Weight
- Data management by patient instead of patch (i.e. multiple patches and devices supply data for one patient)
- Support for VitalPatch 3.0 features including body temperature, 30 degree calibration, and LED blinking.

The following changes were made previously as letters to file: 1.
RGD-007

a. Add support for four 3rd party devices
b. Support body temperature, 30-degree supine posture calibration, and on-command LED blinking
c. Each vital sensor will be assigned a patient ID based upon the actual patient
d. Add support for SPO2 and weight scale and NIBP (related to "a" above)
e. Display graphical ECG streaming data
f. Add combination heart rate / respiratory rate as a new notification; add no data uploading and low battery as error conditions

2. RGD-008
   a. VitalTablet changes – Add support for four (4) third party pulse oximeter (Sp02), non-invasive blood pressure (NIBP) and weight scale devices.
   b. VitalCenter changes - Add support for Sp02, NIBP and weight scale device data displays. Add NEWS calculated with patient vitals, and observer input for consciousness and supplemental oxygen.

RGD-006 – Add new relay hardware (Samsung Galaxy Tab E 8.0 Android OS)
New functionality incorporated which are extensions of previously existing functionality include manual entry of data, notifications on 3rd party devices and body temperature, and universal notifications.

V. INDICATIONS FOR USE

Vista Solution 2.1 is a software user interface intended for use by healthcare professionals to display physiological data collected by the VitalConnect Platform wireless remote monitoring system in home and healthcare settings. Vista Solution is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

Feature	Subject Device	Predicate Device (K170973)
Indications for Use	Vista Solution 2.1 is a software user interface intended for use by healthcare professionals to display physiological data collected by the VitalConnect Platform wireless remote monitoring system in home and healthcare settings. Vista Solution is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.	VitalWatch is a software user interface intended for use by healthcare professionals to display physiological data collected by the VitalConnect Platform wireless remote monitoring system in home and healthcare settings. VitalWatch is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.
Classification	Class II	Class II
Classification Name	Transmitters and Receivers, Physiological Signal, Radiofrequency	Transmitters and Receivers, Physiological Signal, Radiofrequency
Product Code	DRG	DRG
Trade Name	Vista Solution	VitalConnect Platform®, HealthPatch® MD, VitalPatch®, *VitalWatch TM*
Physiological Data Monitored	Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, activity (including step count), and posture (body position relative to gravity including fall) Pulse oximeter, Weight and Blood Pressure via 3rd Party Devices. NEWS score calculated with above patient vitals, and observer input for consciousness and supplemental oxygen.	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)
Principles of Operation	Display of data from validated Relay device using Graphical User Interface (VistaPoint) and transmission of data to Secure Server (VCI Cloud).	Display of data from validated Relay device using third-party developed Graphical User Interface, or VitalWatch, and optional transmission of data to Secure Server.

Electrical safety and electromagnetic compatibility (EMC)
Not Applicable (Standalone Software)

Software Verification and Validation Testing
Software validation was performed in accordance with IEC 62304.

Benchtop Testing
Usability testing was performed in accordance with IEC 62366.

Animal Study
Animal performance testing was not required to demonstrate substantial equivalence to the predicate device.

Clinical Studies
Clinical testing was not required to demonstrate the substantial equivalence of The Proposed Vista Solution Software User Interface. Instead, substantial equivalence is based upon benchtop performance testing.

VII. CONCLUSIONS

The Proposed Vista Solution Software User Interface is substantially equivalent to the predicate device. The modifications described in this 510(k) do not raise different questions of safety and effectiveness.