June 1, 2020

Vitls Inc.
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K191620
Trade/Device Name: Vitls Platform
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, FLL
Dated: April 24, 2020
Received: April 28, 2020

Dear Maureen O'Connell:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191620

Device Name
Vitls Platform

Indications for Use *(Describe)*

The Vitls Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in in healthcare and home settings. This includes heart rate (HR) and body temperature.

The data from the Tego VSS Sensor is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients nor replace standard monitoring and/or routine care.

The device is intended for use as a general patient monitor, to provide physiological information, on patients who are 2 years of age or older.

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

Vitls Platform

Submitter: Vitls Inc.
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Contact Person: Maureen O'Connell
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Phone: 978-207-1245

Date Prepared: May 29, 2020

Trade Name: Vitls Platform

Classification Names: Radiofrequency physiological signal transmitter

Regulation Numbers: 21 CFR 870.2910

Product Codes: DRG

Predicate Devices: Isansys Lifecare Ltd. Patient Status Engine cleared in K172329
Vivalnk FeverScout cleared in K162137

Device Description and Technological Characteristics:

The Vitls Platform is a wireless multi-parameter vital signs monitoring system. The Vitls Platform was developed to include an Application Programming Interface (API) which is intended to allow development of user interface applications, enabling clinicians and medically qualified personnel to access recorded vital signs information for respective analysis only, not for active patient monitoring. The Vitls Platform consists of:

- Wearable device with multiple sensors (the Tego VSS Sensor – An Adhesive Patch with integrated Sensors)
- The Secure Server Library (Cloud-based, including an API)
- The Vitls App (accessible on a smartphone, tablet, PC or

monitor that displays the data and configures the Tego VSS Sensor)

The Tego VSS Sensor is a battery-operated adhesive patch with integrated sensors and wireless transceiver which is worn on the upper body and records heart rate and body temperature. There are two different sizes, one for adult and one for pediatric patients, they are 140 cm and 80 cm in length of the flexible portion of the sensor, respectively. The Tego VSS Sensor continuously gathers multi-parameter vital signs data from the person being monitored and then transmits the encrypted data via bi-directional communication to the third-party connectivity relay, when in range. When not in range, the collected data is stored on the Tego VSS Sensor (for a maximum of 3 hours) and transmitted when a connection with the third-party connectivity relay has been restored. The encrypted wireless data recorded by the Sensor is sent, by the third-party connectivity relay, to the Secure Server. The data may be downloaded from the Secure Server Library or integrated into a Third-Party Application via the APIs of the Secure Server Library. In addition, the wireless data may be transferred to an optional Secure Server Library where they may be stored for future analysis.

Indications for Use:

The Vitls Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in healthcare and home settings. This includes heart rate and body temperature. The data from the Tego VSS Sensor intended for use by healthcare professionals as an aid in the diagnosis and treatment. It is not intended for use on critical care patients nor replace standard monitoring and/or routine care.

The device is intended for use as a general patient monitor, to provide physiological information, on patients who are 2 years of age or older.

Substantial Equivalence Discussion:

Vitls, Inc. believes that the Vitls Platform described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is a Class II medical device. Table 1 provides a tabular presentation of the Vitls Platform compared with the predicate device which is the Isansys Lifecare Ltd. Patient Status Engine cleared in K172329. Additionally, the thermometer feature of the Vitls Platform is supported by an additional predicate device, the Vivalnk FeverScout cleared in K162137 which is described in Table 2.

Table 1
Substantial Equivalence
Vitls Platform (excluding thermometer)

Characteristic	Vitls Platform	Patient Status Engine
Manufacturer	**Vitls, Inc.**	**Isansys Lifecare Ltd.**
510(k) Number	**K191620**	**K172329**
Class	II	II
Device Classification Name	Radiofrequency Physiological Signal Transmitter and Receiver	Radiofrequency Physiological Signal Transmitter and Receiver
Regulation Number	870.2910	870.2910
Product Code	DRG	DRG
Use	Prescription	Prescription
Use Environment	Home and Healthcare Settings	Home and Healthcare Settings
Intended Use	The Vitls Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings.	The Patient Status Engine is intended for use as a general patient monitor, to provide physiological information in home and healthcare settings.
Indications for Use	The Vitls Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in healthcare and home settings. This includes heart rate and body temperature. The data from the Tego VSS Sensor is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients nor replace standard monitoring and/or routine care. The device is intended for use as a general patient monitor, to provide physiological information, on patients who are 2 years of age or older.	The Patient Status Engine 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, heart rate variability (R-R interval), ECG derived respiration rate data (EDR), skin temperature, activity, posture and optional SpO2 and noninvasive Blood Pressure (BP). The device is intended for use on general care patients who are 18 years of age or older as a general

Characteristic	Vitls Platform	Patient Status Engine
		patient monitor, to provide physiological information. The data from the Patient Status Engine is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients nor replace standard monitoring and/or routine care.
Mechanism of Action	Physiological data acquisition (wireless) and display	Physiological data acquisition (wireless) and display
Components	Tego VSS Sensor The Secure Server Library The Vitls App	Patient Gateway (Samsung Tablet) Patient Gateway Software Lifetouch Blue Sensor Lifetemp Sensor Lifeguard Server Software Accessories: Pulse Oximeter Blood Pressure Monitor ECG Electrodes Ambu White Sensors
Physiological Parameters Monitored:		
Heart Rate	Yes	Yes
Heart Rate Variability (HRV)	No	Yes
Respiration Rate	No	Yes
SpO2	No	Optional with FDA cleared SpO2 oximeter
Temperature	Yes (body) @ axilla/armpit	Yes (skin)
Activity	No	Yes (including posture)
Blood Pressure	No	Optional with third party accessory
Sterile	No	No

Characteristic	Vitls Platform	Patient Status Engine
Single Use	Yes	Yes
Battery Operated	Yes	Yes
AC Powered	No	No
Central Server	Yes	Yes
Biocompatible	Yes	Yes

Table 2
Substantial Equivalence
Vitls Platform (thermometer only)

Characteristic	Vitls Platform	Fever Scout Continuous Monitoring Thermometer
Manufacturer	**Vitls, Inc.**	**Vivalnk Inc.**
510(k) Number	**K191620**	**K162137**
Class	II	II
Device Classification Name	Clinical Electronic Thermometereter	Clinical Electronic Thermometer
Regulation Number	880.2910	880.2910
Product Code	FLL	FLL
Use	Prescription	Over-The-Counter
Use Environment	Home and Healthcare Settings	Home and Healthcare Settings
Indications for Use	The Vitls Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in healthcare and home settings. This includes heart rate and body temperature. The data from the Tego VSS Sensor is	The wireless Fever Scout Continuous Monitoring thermometer is a non-invasive and re-usable electronic device for home use. This product is intended for non-urgent ambulatory continuous armpit body temperature monitoring from ages 29 days and older.

Characteristic	Vitls Platform	Fever Scout Continuous Monitoring Thermometer
	intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients nor replace standard monitoring and/or routine care. The device is intended for use as a general patient monitor, to provide physiological information, on patients who are 2 years of age or older.	
Battery	Yes	Yes
Measurement Range	25-45º C	35-42º C
Accuracy	±0.3º C	±0.1º C From 37-39º C ±0.2º C From 35-37º C and 39-42º C
Anatomical Application	Chest and armpit	Armpit peel and stick contact thermometer sensor
Biocompatible	Yes	Yes

Both the Vitls Platform and the Patient Status Engine are wireless physiological monitors. Both systems consist of multiple components including a wireless sensor and data collection system that monitor physiologic parameters. Both systems measure heart rate while the predicate device also measures other physiological parameters sometimes using optional third party accessories. The Vitls platform uses photoplethysmography (PPG) data for all of the monitoring while the predicate uses a combination of ECG and PPG for monitoring. Neither of the systems is provided sterile and both are for single use. Regarding the thermometer functionality, the Vitls Platform's sensor is applied to the chest and armpit while the Fever Scout is applied to the armpit. The measurement range of the Vitls Platform is slightly wider than the Fever Scout.

Performance testing confirmed that the Vitls Platform is substantially equivalent to the predicate devices.

Performance Testing:

The Vitls Platform was tested to recognized consensus standards to confirm that the device is as safe and effective as the predicate device. Specifically:

- Software V&V demonstrates that the device performs as intended
- Biocompatibility testing per ISO 10993-1, 10993-5 and 10993-10 demonstrate that the two patient contacting materials are biocompatible
- Electrical safety testing per IEC 60601-1 shows that the device meets the relevant requirements for electrical safety
- Electrical safety testing per ISO 60601-1-11 shows the device meets the relevant requirements for devices used in home healthcare environment
- Compliance with ISO 80601-2-56 regarding performance of clinical thermometers for body temperature measurement
- Electromagnetic compatibility testing showed the device met the requirements of IEC 60601-1-2, FCC Part 15, Subpart B, Class B, RF Exposure Evaluation per 47 CFR 2.1091 and 2.1093, wireless coexistence per ASNI C63.27.2017 and RF Testing per FCC Part 15, Subpart C, 15.247
- The heart rate feature of the Vitls Platform was compared to the values acquired by an FDA cleared patient monitor, the GE Medical Systems Information Technologies Dash 5000 Patient Monitor (K073462) providing objective evidence that the design outputs for the design inputs as defined in the test protocol have been met with the required confidence and reliability and that there is no greater bias observed in a particular measurement interval

Conclusions:
The Vitls Platform is substantially equivalent to the predicate devices, the Isansys Lifecare Ltd. Patient Status Engine cleared in K172329 and the thermometer feature of the Vitls Platform is supported by an additional predicate device, the Vivalnk FeverScout cleared in K162137. The Vitls Platform has the same intended use and similar technological characteristics as the legally marketed predicate devices and is therefore substantially equivalent to the predicate devices.