November 12, 2024

LifeSignals, Inc.
Saravanan Balasubramanian
Vice President - Global, Medical Technology & Regulatory Operations
426 S Hillview Dr.
Milpitas, California 95035

Re: K242018
Trade/Device Name: UbiqVue™ 2A Multi-parameter System (UX2550)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, MHX, FLL, DQA
Dated: October 10, 2024
Received: October 10, 2024

Dear Saravanan Balasubramanian:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. Shih -S

Jennifer Kozen
Assistant Director
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242018

Device Name

UbiqVue™ 2A Multiparameter System (UX2550)

Indications for Use *(Describe)*

The UbiqVue 2A Multiparameter System is a wireless remote patient monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include electrocardiography (2-Channel ECG), heart Rate, SpO2%, respiration rate, pulse Rate, photoplethysmography waveform, skin temperature, body temperature, body posture, body motion, R-R Interval, heart Rate variability (HRV) and blood Pressure (optional). Data is transmitted wirelessly near real time from UbiqVue 2A Wearable Biosensor and 3rd party device (for Blood Pressure only) to remote central server for display, storage, and analysis.

The UbiqVue 2A Multiparameter System is intended for non-critical, adult population.

The UbiqVue 2A Multiparameter System shall include the ability to notify healthcare professionals through alerts when physiological parameters fall outside the set limits, manual trigger by the patient and to display multiple patient's physiological data for remote monitoring at home and with visual alarm for active monitoring at hospitals and out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.

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.

510(k) Summary for UbiqVue™ 2A Multiparameter System

1 Company name : LifeSignals, Inc.

Address :426 S Hillview Drive
Milpitas, CA 95035.
USA

Contact **:** Saravanan Balasubramanian
Vice President – Global, Medical Technology & Regulatory Operations
Email: saravanan@lifesignals.com
Tel: 510.770.6412 Ext. 4

2 Date prepared : October 07, 2024

3 Device

Trade Name : UbiqVue™ 2A Multiparameter System
Model Name : 2A Multiparameter System
Common Name **:** Transmitters and Receivers, Physiological Signal, Radio Frequency

4 Classification Product code

	Regulation Classification	Product Code	Description
Cardiovascular	21 CFR 870.2910 Class II	DRG	Transmitters and Receivers, Physiological Signal, Radio frequency

5 Subsequent Product code

	Regulation Classification	Product Code	Description
Cardiovascular	21 CFR 870.1025 Class II	MHX	Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)
General Hospital	21 CFR 880.2910 Class II	FLL	Thermometer, Electronic, Clinical

	Regulation Classification	Product Code	Description
Anesthesiology	21 CFR 870.2700 Class II	DQA	Oximeter

6 Predicate & Reference Devices

Primary Predicate Device:
510(k) Number : K202868
Model : LifeSignals Multiparameter Remote Monitoring Platform
Manufacturer : LifeSignals, Inc. USA

Secondary Predicate (for SpO2 , Pusle Rate & Body temperature intended use):
510(k) Number : K212153
Model : Biobeat Platform, BB-613WP Patch
Manufacturer : Biobeat Technologies Ltd. Israel

Reference Device-I (for Body temperature, HRV, RR Interval, EWS Intended Use):
510(k) Number : K183078
Model : Vitalconnect Platform, VitalPatch Biosensor
Manufacturer : Vital Connect, Inc. USA

Reference Device -II (for SpO_2, Pulse Rate, PPG & SQI technology):
510(k) Number : K200160
Model : 740 SafeSAT
Manufacturer : Zoe Medical, Inc. USA

Reference Device-III (for Visual Alarm & Active Monitoring Intended Use):
510(k) Number : K160951
Model : Philips Efficia CMS200 Central Monitoring System
Manufacturer : Philips Medical Systems, USA

Reference Device-IV (for Body Temperature accuracy claim):
510(k) Number : K203215
Model : Radius T Wearable Thermometer
Manufacturer : Masimo Corporation, USA

7 Device description

The UbiqVue™ 2A Multiparameter System is similar to LifeSignals Multiparameter Remote Monitoring Platform that is cleared under K202868 but upgraded with monitoring of additional physiological parameters, minor performance improvements and additional User Interface.

The UbiqVue™ 2A Multiparameter System consists of following components:

1) UbiqVue™ 2A Wearable Biosensor
2) UbiqVue™ Single Patient Relay
3) UbiqVue™ Multi-Patient Relay
4) UbiqVue™ Central Server
5) UbiqVue™ Active Monitoring Portal
6) UbiqVue™ Relay Bridge Software (optional)
7) UbiqVue™ Bluetooth Gateway Software (optional)
8) Third-party Blood Pressure device (optional)

- The ***UbiqVue™ 2A Wearable Biosensor*** when attached to body acquires two channels of ECG signals, TTI respiration signals (one of the inputs for deriving Respiration Rate), resistance variation of a Thermistor attached to body (used for deriving Skin Temperature) & accelerometer data (input for deriving Respiration Rate & Posture), pre-processes them and wirelessly transmits to a paired Relay device, as cleared under K202868.

  Following are additional features proposed in this submission:

  - Ambient temperature sensor for Body temperature derivation.
  - Acquisition of PPG (Photoplethysmography) signals using the integrated Optical sensor array.
  - Derivation of SpO2% and Pulse Rate within the Biosensor, based on PPG signals acquired through the Optical sensor array.

  Biosensor uses standard WLAN (802.11b) secured (AES) communication protocol for wireless data transmission to the Relay Device, as cleared under K202868. The Biosensor is also additionally integrated with BLE Radio for communication with Single Patient Relay device.

  As cleared under K202868, when Relay device is available within the wireless range, the acquired data is continuously transmitted to the Relay device immediately. If Relay device is not available or if there is any interruption in the communication between Relay device and Biosensor, data shall be temporarily buffered locally in Biosensor till the wireless connection is re-established.

- The ***UbiqVue™ Single Patient Relay Device,*** a standard Mobile device or custom device that is installed with a UbiqVue Single Patient Relay Application software, that receives the physiological data transmitted from any paired Biosensor. It shall transmit the data received from the Biosensor, immediately without any day to Central Server that is configured to receive, after necessary data encryption. The Single Patient Relay Device shall receive data from Biosensor either through WLAN or BLE and transmit it to Central Server using its mobile data network (3G, 4G, LTE, 5G, etc.)
  Single Patient Relay Device function is identical to the one cleared under K202868, except it is upgraded to support additional parameters & also improvements in GUI as below:
  - To handle additional data packets of Biosensor such as Ambient Temperature, PPG signals, SpO2% and Pulse Rate.
  - Interactive GUI that provides feedback to Users about the signal quality of PPG signals to identify the optimal body location for affixing the Biosensor.
  - Shall pair with a 3rd party Blood Pressure device using BLE and transfer the data to the Central Server.
  - Allows User to enter Oral Temperature reading (for calibration) and/or manual Blood pressure data (optional if no 3rd Party device is connected).

- The ***UbiqVue™ Multi-Patient Relay Device (MPR)*** is an UbiqVue™ Multi-Patient Relay Application Software installed in a standard Linux platform (Physically or in cloud), that has ability to pair & receives data from multiple Biosensors, through wireless access points (WLAN) connected in its network. It shall transmit the received data from Biosensors to Central Server that is configured to receive through internet or private network (VPN), after necessary encryption & authentication. Multi-Patient Relay Device also receives data from multiple third-party Blood Pressure devices worn by the patients & connected to its network (through BLE gateway).
  If the Central Server is not available or there is no connectivity, the data shall be temporarily buffered securely in the MPR device itself. There is no GUI component for this software application.

- The ***UbiqVue™ Central Server*** is UbiqVue™ Central Server Application software installed in a compatible Linux Server hardware Platform. The Central Server Application functions are also identical to Secure Server Application in LifeSignals Multi-parameter Remote Monitoring Platform (K202868), other than being upgraded to handle additional parameters. Also, the "Sensor Processing Library", the algorithm that derives various vital parameters is upgraded for performance improvements. The following are additional features:
  - Extending the minimum skin temperature measurement capability from 32.0°C (89.6 °F) to 15.0°C (59.0°F)

- Body Temperature estimation using Skin Temperature, Ambient temperature, Heart Rate (based on clinical condition) and Activity.
- Uses the Oral Temperature entered manually for initial / periodic calibration of derived Body temperature.
- Additional Posture classification & Body motion detection capabilities.
- Improvements in Respiration Rate & Heart Rate derivation algorithm.
- Integration with 3rd Party beat analysis & classification software for deriving Sinus Heart Rate, R-R Interval & Heart Rate Variability.
- The PPG Signal Quality Index (SQI) algorithm module for displaying the SQI on the Active Monitoring dashboard & to access the quality of SpO2 value derived by the Biosensor.
- Support for Early Warning Score (NEWS2) calculation.

Central Server shall have ability to send alert notifications to any configured one or more Users through E-mail, SMS or WhatsApp, for any Clinical, Technical or Manual Alert conditions, as cleared under K202868. However, this alert engine is upgraded to support additional parameters and improved configuration capabilities such as Acknowledgement, priority & condition delay time.

- ***Active Monitoring Portal*** in UbiqVue™ 2A Multiparameter System is identical to Web UI in LifeSignals Multi-parameter Remote Monitoring Platform cleared under K202868. It is a browser-based User Interface Application that enables Clinical personnel to login to the Central server remotely and access the patient physiological data (Biosensor & derived data) and view/Acknowledge the Alert(s). The Clinical personnel, depending on the roles (normal or supervisory) can access data of multiple patients assigned to them and search them based on the recent alert status. This includes patients that are active (wearing Biosensor) and monitoring procedures completed.
  It is in-built with a Monitoring Dashboard that continuously displays physiological parameters, waveforms & alert status of any assigned patients to any authenticated Clinical personnel for (quasi) real time Active Monitoring. It has the option for the User to select multiple patient tile view or Single Patient Zoom View/Hybrid view of any patient based on multiple available filter settings.
  Following are the few changes in this 510(k):

  - Additional parameters (SpO2%, PR, EWS, SYS, DIA, MAP, PPG, SQI, EWS).
  - Visual alarm display for any Clinical, Technical, or manual alert/alarm.
  - Hybrid tile view (Zoom View + Tile view) and Group tile view.
  - Multi-level User Management, roles & privileges.

  Note: Any Third-Party Application / Server may communicate with UbiqVue™ Central Server using a defined set of Application Programming Interface (API) for entering patient information, configuring & generating customized report or any other requirement that

does not alter the intended use of the system (e.g., EMR/EHR, HIMS) or to meet the additional intended use claimed by the third-party application. UbiqVue™ Active Monitoring Portal shall continue to be used for the claimed Active Monitoring intended use. However, UbiqVue™ Active Monitoring portal may be optional for integration with any other regulatory approved monitoring dashboard or different intended use claims.

- ***Relay Bridge Software*** in UbiqVue™ 2A Multiparameter System when installed in a standard OpenWrt based routers, shall provide communication between Biosensor(s) & Multi-Patient Relay. Relay Bridge is an alternate for a standard access point and is intended when Multi-Patient Relay Software is hosted in the cloud. Similar to standard access point, the Relay Bridge communicates with multiple Biosensor and transfers the data to the Multi-Patient Relay without buffering the data. Since the Relay bridge transfers the data to the designated Multi-Patient Relay bridge in the cloud, it further encrypts the data for securely transmitting through the internet via ethernet, Wi-Fi or cellular network.

- ***Bluetooth Gateway Software*** in UbiqVue™ 2A Multiparameter System when installed in a standard OpenWrt based BLE gateway or BLE supported routers, shall provide communication between 3rd party BLE devices (e.g. BP device) & Multi-Patient Relay. Bluetooth Gateway communicates with multiple 3rd party devices and transfers the data to the Multi-Patient Relay without buffering.

8 Indications for Use

- The UbiqVue 2A Multiparameter System is a wireless remote patient monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include electrocardiography (2-Channel ECG), heart rate, SpO2%, respiration rate, pulse rate, photoplethysmography waveform, skin temperature, body temperature, body posture, body motion, R-R Interval, heart Rate Variability (HRV) and Blood Pressure (optional). Data is transmitted wirelessly near real time from UbiqVue 2A Wearable Biosensor and 3rd party device (for Blood Pressure only) to remote central server for display, storage, and analysis.
- The UbiqVue 2A Multiparameter System is intended for non-critical, adult population.
- The UbiqVue 2A Multiparameter System shall include the ability to notify healthcare professionals through alerts when physiological parameters fall outside the set limits, manual trigger by the patient and to display multiple patient's physiological data for remote monitoring at home and with visual alarm for active monitoring at hospitals and out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.

9 Substantial Equivalence comparison (Subject device & Predicate Device)

Comparison	Predicate-I (K202868)	Predicate-II (K212153)	Subject Device
Manufacturer	LifeSignals, Inc., USA	Biobeat Technologies Ltd.	LifeSignals, Inc., USA
Product Codes	DRG, MHX, FLL	DQA, DRG, BZQ, DXG, FLL	DRG, MHX, FLL, DQA
Regulation Classification (Primary)	21 CFR 870.2910 Class II	21 CFR 870.2700 Class II	21 CFR 870.2910 Class II
Intended use / Indications for use	The LifeSignals Multi-Parameter Remote Monitoring Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include Electrocardiography (2-channel ECG), Heart Rate, Respiration Rate, Skin Temperature & Posture. Data is transmitted wirelessly from LifeSignals Biosensor to Remote secure server for display, storage & analysis. The LifeSignals Multi-Parameter Remote Monitoring Platform is intended for non-critical, adult population. The LifeSignals Multi-Parameter Remote Monitoring Platform can include the ability to notify healthcare professionals when physiological parameters fall outside the set limits and to	The Biobeat Platform is a wireless noninvasive remote monitoring system intended for use by healthcare professionals for spot-checking collection of physiological data in home and healthcare settings. This can include, **functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, blood pressure,** respiration rate (RRp), and **body temperature.** The Biobeat Platform tracks changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulsemeasurements from the integrated SpO2 sensor, following a calibration process using an FDA-cleared oscillometric blood pressure monitor. The Biobeat Platform is intended for spot- checking and tracking changes of adult patients in	The UbiqVue™ 2A Multiparameter System is a wireless remote patient monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include electrocardiography, heart rate, **SpO2%**, respiration rate, **pulse rate**, **photoplethysmography waveform**, skin temperature, **body temperature**, body posture, **body motion**, **R-R Interval**, **heart rate variability (HRV)** and Blood Pressure (optional). Data is transmitted wirelessly near real time from UbiqVue 2A Wearable Biosensor and 3rd party device (for Blood Pressure only) to Remote Central server for display, storage, and analysis. The UbiqVue™ 2A Multiparameter System is intended for non-critical, adult population. The UbiqVue™ 2A Multiparameter System shall include the ability to

Comparison	Predicate-I (K202868)	Predicate-II (K212153)	Subject Device
	display multiple patient physiological data for remote monitoring.	hospitals, clinics, long-term care, and at home . The data from the Biobeat 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.	notify healthcare professionals through alerts when Physiological parameters fall outside the set limits, manual trigger by patient and to display multiple patient's physiological data for remote monitoring at home and with visual alarm for active monitoring **at hospitals and out of hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.**
Intended Population	Non-critical, adult population, 18 years or older	Non-critical, adult population, 18 years or older	Non-critical, adult population, 18 years or older
Intended Use Environment	Home & Healthcare settings	Home & Healthcare settings	Home & Healthcare settings
Monitored Parameters			
ECG (Two Channel)	✓	×	✓
Heart Rate	✓	×	✓
Heart Rate Variability	×	×	✓
R-R Interval	×	×	✓
Respiration Rate	✓	✓	✓
Skin Temperature	✓	×	✓
Body Temperature	×	✓	✓
Body Posture	✓	×	✓
Body Motion	×	×	✓
SpO2%	×	✓	✓

Comparison	Predicate-I (K202868)	Predicate-II (K212153)	Subject Device
Pulse Rate	×	✓	✓
PPG Waveform	×	✓	✓
Blood Pressure	×	✓	✓ (using 3rd party device)
Continuous Physiological data monitoring	✓	× (Spot check only)	✓
Heart Rate Range	30 – 250 BPM	×	30 – 250 BPM
Accuracy	± 3 BPM or 10% whichever is greater	×	± 3 BPM or **5%** whichever is greater
Respiration Rate Range	6-60 Breaths per Minute	4-40 Breaths per Minute	5-60 Breaths per Minute
Accuracy	≤ 1 Breath per minute (Mean Absolute Error based on Simulation study) ≤ 3 Breaths per minute (Mean Absolute Error based on Clinical study)	± 3 Breaths per Minute	≤ 1 Breath per minute (Mean Absolute Error based on Simulation study) ≤ 3 Breaths per minute (Mean Absolute Error based on Clinical study)
Method	Trans-thoracic Impedance (TTI), ECG Derived Respiration (EDR) based on RS Amplitude and Accelerometer data.	Derived from PPG photoplethysmogram	Trans-thoracic Impedance (TTI), ECG Derived Respiration (EDR) based on RS Amplitude & **Respiratory Sinus arrhythmia (RSA)** and Accelerometer data.
Skin Temperature Range	32.0°C – 43.0°C 89.6°F – 109.4°F	×	**15.0°**C – 43.0°C **59.0°F** – 109.4°F
Accuracy	As per ASTM E1112-00	×	As per ASTM E1112-00
Body Temperature Range	×	32.0°C – 43.0°C 89.6°F – 107.6°F	32.0°C – 43.0°C 89.6°F – 109.4°F

Comparison	Predicate-I (K202868)	Predicate-II (K212153)	Subject Device
Clinical Accuracy	×	±0.3°C	-0.27 °C (Clinical Bias) 1.01°C (Limits of agreement)
Method	×	Adjusted mode (with Skin Temperature & Ambient Temperature)	Adjusted mode (with Skin Temperature, Ambient Temperature, Heart Rate & Activity)
Posture Detection	Lying down, Upright or Inclined	×	Supine, Prone, Lying- Left/Right, Reclining, Reclining-Left/Right, Leaning Forward, Upright, Upside down
SpO2% Range	×	40 to 100%	0 to 100%
Accuracy	×	± 2 %	± 3 % (100 to 70%), Less than 70% unspecified
PPG	×	✓	✓
Signal Strength Indicator	×	×	✓
Measurement Site	×	Chest	Chest
Optical Sensor	×	880nm (IR), 650nm (Red)	Spectral Sensor
Pulse Rate Range	×	40 to 250 BPM	30 to 250 BPM
Accuracy	×	± 3%	± 3 or 5% whichever is greater
R-R Interval	×	×	✓
Beat Classification	×	×	✓
Sinus Heart Rate	×	×	✓
Heart Rate Variability (HRV) SDNN	×	×	✓
SDANN	×	×	✓

Comparison	Predicate-I (K202868)	Predicate-II (K212153)	Subject Device
ASDNN	×	×	✓
RMSSD	×	×	✓
VLF Band	×	×	✓
LF Band	×	×	✓
HF Band	×	×	✓
Body Motion	×	×	No Body Motion, Mild Body Motion, Moderate Body Motion, Severe Body Motion
Sensor			
Single Use	✓	✓	✓
Wear Life	120 hours	120 hours	120 hours
Dimension	105 x 94 x 12 mm	Monitor enclosure - 38 x 38 x 15 mm. Adhesive unit - 85 x 85 x 12 mm	116 x 91 x17 mm
Weight	28 g	14g	35 g
ECG Electrode distance ECG-A ECG-B	 90.0 mm 57.9 mm	×	 90.0 mm 73.0 mm
Location of Body	Upper Left Chest	Chest-patch attached to the skin & Wrist device	Upper Center Chest or Upper Left Chest
Data can be transferred & temporarily stored	✓	✓	✓
Battery	Li-MnO2 (Primary)	Li-MnO2 (Primary)	Li-MnO2 (Primary)
Applied part category	Type CF	Type BF	Type CF
Defibrillation Proof	✓	×	✓
HF Surgical equipment compatibility	✓	×	✓
Communication protocol	WLAN (802.11b)	BLE 4.2	WLAN (802.11b), BLE 5.2
Wireless Radio Frequency	2.4 - 2.4835 GHz	2.402-2.480 GHz	2.4 - 2.4835 GHz

Comparison	Predicate-I (K202868)	Predicate-II (K212153)	Subject Device
Communication Security	WPA2-PSK/CCMP	AES-CCM 128	WPA2-PSK /CCMP AES-CCM 128
Patient Relay Device			
Authentication from Server	✓	-	✓
Data transferred to Server	✓	✓	✓
Data buffered if there is no connection with Server	✓	✓	✓
GUI for Patient admission (Only for Single Patient Relay)	✓	-	✓
GUI for PPG signal quality (Only for Single Patient Relay)	✗	-	✓
Secure Server	Data is stored for access by Active Monitoring Portal & any 3rd party server (through API)	-	Data is stored for access by Active Monitoring Portal & any 3rd party server (through API)
Programmable Alert Notification & Configurable	✓ (Clinical, Technical, Manual)	-	✓ (Clinical, Technical, Manual)
Early Warning Score (NEWS2)	✗	-	✓
Active Monitoring Portal			
Multi-patient Tile view	✓	-	✓
Single Patient Zoom view	✓	-	✓
Visual Alarm Indication	✗	-	✓
Early Warning score	✗	-	✓

Note: ✓Feature is identical *✗Feature not available* - Feature Unknown

Differences and Risks associated with that:

- The Subject device has additional physiological data monitoring capabilities of, R-R interval, Heart Rate Variability & Body motion in the system, compared the Predicate device(s). However, performance of these parameters is validated & the technology to measure these parameters is equivalent to other 510(k) cleared device which is included as Reference Device-I under Section #10 below (K183978). Hence, these additional parameters do not affect the intended use of the Proposed device.
- The Subject device has an Early Warning Score display in the Active Monitoring dashboard as an added feature, compared to the Predicate Device(s). However, this does not add any risk, as Early Warning Score is based on well-known NEWS2 (National Early Warning Score by Royal College of Physicians, UK) adopted by other 510(k) cleared device which is included as Reference Device-I section #10 (K183078) and the integration of which is validated.
- The Subject device has improved algorithms to derive Respiration Rate with additional Respiratory Sinus arrhythmia (RSA) based EDR, derive Heart Rate from either of the two channels dynamically & extended Skin temperature compared to the Predicate device. However, performance of improved Respiration Rate, Heart Rate & Skin temperature algorithm is validated and hence does not add any risk.
- The Subject device has a Visual Alarm indication and intended for Active monitoring at hospitals & out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals, using the updated Active Monitoring portal. However, this does not add any risk, as the Visual Alarm indication is in compliance with IEC 60601-1-8 and Intended use is equivalent to other 510(k) cleared device which is included as Reference Device-III under Section #10 (K160951)
- The Subject Device uses IR/Red/White LED and Spectral sensor for continuous SpO2% & Pulse rate derivation compared to the standard IR/Red LED/sensor used in the Predicate device. However, performance of these parameters is validated & the technology to measure these parameters is equivalent to other 510(k) cleared device which is included as Reference Device-II under Section #10 (K200160).
- The Body temperature accuracy claim of the predicate device is different from the subject device. However, the accuracy claims of the Reference Device-IV (K203215) that is included under Section #10 is same as the subject device.

10 Comparison with Reference devices for additional physiological monitoring parameters & Technology.

Comparison	Reference Device - I (K183078)	Reference Device - II (K200160)	Reference Device- III (K160951)	Reference Device- IV (K203215)	Subject Device
Manufacturer	Vital Connect, Inc.	Zoe Medical, Inc.	Philips Medical Systems	Masimo Corporation	LifeSignals, Inc., USA
Product Codes	DRG, MHX, DSI	MWI, DQA, DXN	MSX	FLL	DRG, MHX, FLL, DQA
Regulation Classification (Primary)	21 CFR 870.2910 Class II	21 CFR 870.2300 Class II	21 CFR 870.2300 Class II	21 CFR 880.2910 Class II	21 CFR 870.2910 Class II
Intended use / 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	The 740 SafeSAT is indicated for use as a bedside, portable device for use by health care professionals, clinicians and medically qualified personnel for spot checking, continuous monitoring and recording of adult and pediatric patients, excluding neonates. The Monitor features technology to facilitate the	The Efficia CMS200 central monitoring system is intended for use by healthcare professionals for central viewing of physiologic waves, parameters, and trends from other networked medical devices (patient monitors and vital signs monitors) for multiple patients. It provides secondary operator notification of alarms from other networked medical devices. It provides for the	Radius T wearable thermometer is intended for single-use, continuous noninvasive measurement of body temperature on the upper chest via wireless communication to a smart device application or compatible patient monitor (i.e., Masimo Root, Masimo Rad-97). The Radius T is indicated for single-use, continuous body	The UbiqVue™ 2A Multiparameter System is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include electrocardiography, heart rate, SpO2%, respiration rate, pulse rate, photoplethysmography waveform, skin temperature, body temperature, body posture, body motion, R-R Interval, heart rate Variability (HRV) and Blood Pressure (optional). Data is transmitted

Comparison	Reference Device - I (K183078)	Reference Device - II (K200160)	Reference Device- III (K160951)	Reference Device- IV (K203215)	Subject Device
	(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 Vital Connect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment.	monitoring of non-invasive blood pressure, pulse rate and functional arterial oxygen saturation (SpO_2) in a variety of clinical environments.	retrospective review of alarm conditions, physiologic waves and parameters from multiple patients. The intended use of the printer, when present, is to provide hardcopy text, graphics, and wave data. The Efficia CMS200 may provide for connection and information exchange to external systems. The Efficia CMS200 is intended for u**se in hospitals and out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare Professionals.**	temperature measurements of persons 5 years of age or older in hospitals, hospital-type facilities, and home environments.	wirelessly near real time from UbiqVue 2A Wearable Biosensor and 3rd party device (for Blood Pressure only) to remote central server for display, storage, and analysis. The UbiqVue 2A Multiparameter System is intended for non-critical, adult population. The UbiqVue 2A Multiparameter System shall include the ability to notify healthcare professionals through alerts when physiological parameters fall outside the set limits, manual trigger by the patient and to display multiple patient's physiological data for Remote monitoring at home and with visual alarm for active monitoring **at hospitals and out of- hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.**

Comparison	Reference Device - I (K183078)	Reference Device - II (K200160)	Reference Device- III (K160951)	Reference Device- IV (K203215)	Subject Device
Intended Population	General care patients who are 18 years or older	General & Acute care Adult and Pediatric Patients	General patients	5 years or older	Non-critical, adult population, 18 years or older
Intended Use Environment	Home & Healthcare settings	Healthcare Settings	Healthcare Settings	Home & Healthcare settings	Home & Healthcare settings
Monitored Parameters					
ECG	✓ (Single Channel)	×	✓	×	✓ (Two Channels)
Heart Rate	✓	×	✓	×	✓
Heart Rate Variability	✓	×	✓	×	✓
R-R Interval	✓	×	✓	×	✓
Respiration Rate	✓	×	✓	×	✓
Skin Temperature	✓	×	×	×	✓
Body Temperature	✓	×	✓	✓	✓
Body Posture	✓	×	×	×	✓
Activity / Body Motion	✓ (Activity)	×	×	×	✓ (Body motion)
SpO2%	×	✓	✓	×	✓
Pulse Rate	×	✓	✓	×	✓
PPG Waveform	×	✓	✓	×	✓
Blood Pressure	×	✓	✓	×	✓ (using 3rd party device)
Continuous Physiological data monitoring	✓	✓	✓	✓	✓

Comparison	Reference Device - I (K183078)	Reference Device - II (K200160)	Reference Device- III (K160951)	Reference Device- IV (K203215)	Subject Device
Body Temperature Range	32.0°C – 43.0°C 89.6°F – 109.4°F	×	–	**25.0°C – 43.0°C 77.0°F – 109.4°F**	32.0°C – 43.0°C 89.6°F – 109.4°F
Clinical Accuracy	≤ 1°C (Mean absolute error)	×	–	**-0.27 °C** (Clinical Bias) **≤1.0°C** (Limits of agreement)	**-0.27 °C (Clinical Bias) 1.01°C (Limits of agreement)**
Method	Adjusted mode (with Skin Temperature & Ambient Temperature)	×	–	**Adjusted mode (surface temperature)**	**Adjusted mode (with Skin Temperature, Ambient Temp, Heart Rate & Activity)**
SpO2% Range	×	0 to 100%	–	×	0 to 100%
Accuracy	×	± 2 % (100 to 70%), Less than 70% unspecified	–	×	± 3 % (100 to 70%), Less than 70% unspecified
PPG	×	✓	–	×	✓
Signal Strength Indicator	×	✓	–	×	✓
Method	×	LED - Red, IR & White Two Photo sensor	–	×	LED - Red, IR & White Two Photo sensor
Pulse Rate Range	×	30 to 250 BPM	–	×	30 to 250 BPM
Accuracy	×	± 3 or 5% whichever is greater	–	×	± 3 or 5% whichever is greater
R-R Interval	✓	×	–	×	✓

Comparison	Reference Device - I (K183078)	Reference Device - II (K200160)	Reference Device- III (K160951)	Reference Device- IV (K203215)	Subject Device
Beat Classification	✓	×	–	×	✓
Sinus Heart Rate	✓	×	–	×	✓
Heart Rate Variability (HRV)	✓	×	–	×	✓
Monitoring Dashboard					
Multi-patient Tile view	✓	×	✓	×	✓
Single Patient Zoom view	✓	✓	✓	×	✓
Visual Alarm Indication	×	✓	✓	×	✓
Viewing the Trend	✓	×	✓	×	✓
Early Warning Score (NEWS2)	✓	×	×	×	✓

Note: ✓ *Feature is identical* × *Feature not available* - Feature Unknown

- The function of Active Monitoring portal of the Subject device at hospitals & out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals is equivalent to the Reference device-III. The Reference device-III obtains data from networked patient monitors, while the subject device obtains data from the networked Biosensors. Both Subject device & Reference device-III provide centralized viewing of waveforms, numeric data and alarms from all the connected beds. Both Reference Device-III & Subject device allow for retrospective data review and can transfer data to an electronic medical record system (EMR).
    - One main difference between the Reference Device-III & Subject device is that the Reference Device-III provides secondary alarm notification (both audio & visual), while the Subject device provides primary visual alarm notification. The Subject device Portal does not have the claims of audio alarm. The Reference Device-III software is intended to be installed in a dedicated PC that meets the audio alarm specification, while the subject device is browser-based solution & not specific to any specific hardware (PC). However, the alert notification (e.g. Email or SMS) by the Subject device can be configured to be an audible one and further not intended for critical patients. Hence, this does not add any risk.
- The Subject device uses the same technology of three LED & two photosensors used in Reference device-II. However, the location of SpO2 monitoring in Subject device is on "Chest", while it is "Finger" in the Reference device-II. However, the sensor design is suitably modified for the "Chest" based measurement and the performance of SpO2% & Pulse Rate on "Chest" is validated through hypoxia tests as per ISO80601-2-61. Further, the subject device has additional controls for Chest-based measurement, such as providing visual guidance to the User to identify suitable location on the Chest for affixing the Biosensor. All the subject device has an in-built algorithm to invalidate or discard the derived SpO2% & Pulse rate value if there is a severe body motion or heavy respiration, by accessing the PPG signal & accelerometer data. Hence, this does not add any risk.

11 Summary of Performance Testing

Verification & Validation activities were performed on UbiqVue™ 2A Multiparameter System to demonstrate substantial equivalence to the predicate device:

- Biocompatibility testing of In-vitro cytotoxicity, skin irritation and skin sensitization were conducted on UbiqVue™ 2A Wearable Biosensor, according to *ISO 10993-1: 2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*.

- Electrical Safety and electromagnetic compatibility testing were conducted on UbiqVue™ 2A Multiparameter System with UbiqVue™ 2A Wearable Biosensors for compliance with *IEC 60601-1(Ed.3.2), IEC 60601-1-2 (Ed. 4.1)* and IEC *60601-1-11(Ed. 2.1)*.

- UbiqVue™ 2A Multiparameter System with UbiqVue™ 2A Wearable Biosensors (at Upper Center Chest location & Upper Left Chest location) were verified & validated for compliance with ISO *80601-2-61(Ed. 2.0)* standard including clinical validation to determine the accuracy of SpO_2% with respect to SaO2 values from simultaneously drawn arterial blood.

- The Pulse Rate accuracy performance of UbiqVue™ 2A Multiparameter System was verified by using bench testing, as per ISO *80601-2-61(Ed. 2.0)* and through clinical validation by a reference device.

- Body temperature accuracy performance of UbiqVue™ 2A Multiparameter System was validated using non-randomized, self-control comparative on-body comparative performance with oral digital thermometer on multiple subject populations in accordance with the *ISO 80601-2-56 (Ed.2.0)*.

- The Skin temperature accuracy performance of UbiqVue™ 2A Multiparameter System was reverified by using bench testing, as per *ASTM E1112-00 & ISO80601-2-56 (Ed. 2.0)*.

- ECG & Heart Rate Performance testing was repeated on the UbiqVue™ 2A Multiparameter System for compliance with *ANSI AAMI IEC 60601-2-47:2012, IEC 60601-2-27(Ed.3.0) & IEC 60601-2-25 (Ed. 2.0)*.

- Wear-life performance of ECG waveform quality, Heart Rate, Respiration Rate, Skin Temperature, and SpO2% of UbiqVue™ 2A Multiparameter System under normal use condition was validated using non-randomized, self-control comparative on-body comparative performance study for the wear period of 120 hours.

- Improvement in the Respiration algorithm was validated by comparing against clinician manually scored end tidal CO2 (EtCO2) capnography, under spontaneous breathing & metronome breathing during normal activity conditions as part of wear-life study.

- The Alert system & Visual alarm display on UbiqVue™ 2A Multiparameter System was validated for compliance with *IEC 60601-1-8 (Ed. 2.2)*.

- Usability study was conducted on UbiqVue™ 2A Multiparameter System for compliance with *IEC 60601-1-6 (Ed. 3.2)* and *"USFDA Guidance- Applying Human Factors and Usability Engineering to Medical Devices."*

- Wireless performance & coexistence testing conducted as per *ANSI/IEEE C63.27:2017: American National Standard for Evaluation of Wireless coexistence* on UbiqVue™ 2A Multiparameter System for both Single Patient Relay System & Multi-Patient Relay System.

- Software in the UbiqVue™ 2A Multiparameter System was designed, documented, verified & validated as per the *IEC 62304: Medical device Software - Software Life Cycle Process* and USFDA *Guidance for the content of premarket submissions for Software contained in medical device*. The Software for this device is determined as Class B, "Moderate-Enhanced documentation" level of concern.

- Software in the UbiqVue™ 2A Multiparameter System was securely designed by conforming to *IEC 81001-5-1 Health software and health IT systems safety, effectiveness and security – Activities in the product life cycl*e.

- Shelf-life & Reliability and testing were conducted and verified on UbiqVue™ 2A Wearable Biosensor, as per the acceptance criteria.

- Packaging test conducted on the packaged UbiqVue™ 2A Wearable Biosensors as per *ASTM D7386-16.*

12 Conclusion

The UbiqVue 2A Multiparameter System is substantially equivalent in indications for use & intended use to the legally marketed Predicate Device(s) & Reference Device(s). The Technology adopted for additional physiological parameters in UbiqVue 2A Multiparameter System is substantially equivalent to the technology adopted in the Reference Device(s). Minor differences between UbiqVue 2A Multiparameter System and the Predicate & Reference devices have no significant effect on safety or effectiveness, as established through various performance tests. Thus, the proposed device/system is substantially equivalent to the legally marketed predicate & reference devices.