July 21, 2021

LifeSignals, Inc.
% Rita King
Chief Executive Officer and Senior Regulatory Consultant
MethodSense, Inc.
One Copley Parkway, Suite 410
Morrisville, North Carolina 27560

Re: K202868
Trade/Device Name: LifeSignals Multi-Parameter Remote Monitoring Platform
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, MHX, FLL
Dated: July 15, 2021
Received: July 16, 2021

Dear Rita King:

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
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)*

K202868

Device Name

LifeSignals Multiparameter Remote Monitoring Platform

Indications for Use *(Describe)*

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 display multiple patient physiological data for remote monitoring.

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 for
LifeSignals Multi-parameter Remote Monitoring Platform

1 Company name :LifeSignals, Inc.

Address :39355 California Street, Suite 305
Fremont, CA 94538.
USA

Contact :Saravanan Balasubramanian
Vice President – Medical Systems & Regulatory Affairs
Email: saravanan@lifesignals.com
Tel: 510.770.6412 Ext. 4

2 Date prepared : July 20, 2021

3 Device

Trade Name : LifeSignals Multi-parameter Remote Monitoring Platform
Model Name : Multi-parameter Remote Monitoring Platform
Common Name : Wireless Multi-parameter Remote Monitoring System

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

6 Predicate & Reference Devices

Predicate Device :

510(k) Number : K163453
Model : VitalConnect Platform
Manufacturer : Vital Connect, Inc. USA

Reference Device – I (for "*Remote Monitoring Dashboard"* only):

510(k) Number : K170973
Model : VitalWatch Software User Interface
Manufacturer : Vital Connect, Inc. USA

Reference Device – II (for technology comparison):

510(k) Number : K200690
Model : LifeSignals ECG Remote monitoring Patch Platform
Manufacturer : LifeSignals, Inc. USA

7 Device description

LifeSignals Multi-parameter Remote Monitoring Platform consists of four main components:

(1) LifeSignals Multi-parameter Biosensor
(2) LifeSignals Relay device (Software Application)
(3) LifeSignals Secure Server (Software Application)
(4) Web UI /Remote Monitoring Dashboard

- ***LifeSignals Multi-parameter Biosensor*** when attached body acquires two channel of ECG signals, TTI respiration signals (one of the input 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 (or any Receiver system). 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.

  Biosensor Patch uses standard WLAN (802.11b) secured (AES) communication protocol for wireless data transmission to the Relay Device.

- ***Relay Device*** manages wireless communication between LifeSignals Biosensor and LifeSignals Remote Secure Server. Relay device is a LifeSignals Relay Application software installed in a compatible commercial hardware platform, like a mobile phone or a tablet.

- ***LifeSignals Relay (Application)*** functions include*:*
  - Manages secured wireless communication (WLAN 802.11b) between Relay device & Lifesignals Biosensor and encrypted communication between the Relay device and the LifeSignals Remote Secure Server.
  - Receives physiological signals from the Biosensor and transmit them after encryption to Secure Server as quickly as possible. It manages the database in Relay device for buffering/storing the data securely, if there is any disruption in communication with the Secure Server.
  - Provides user interface for entering the Biosensor & Patient information and pairing & establishing connection with the Biosensor.
  - Provides User Interface to record any manual alert events by the patient.

- ***Secure Server*** is a LifeSignals Secure Server Application software installed in Linux-compatible Secure server hardware platform.

  LifeSignals Secure Server Application manages the decryption, uploading and storage of Biosensor data received from multiple authenticated Relay devices. The "*Sensor Processing Library"* in LifeSignals Secure Server process, filter the received Biosensor data and derives Heart Rate, Respiration Rate, Skin Temperature & Posture before storing them in a secured location along with received Biosensor data, for access by Web UI or any 3rd-party applications for display or analysis purpose.

  LifeSignals Secure Server Application shall have an optional ability to send alert notifications to any configured destination (email, SMS, WhatsApp), when the parameters (Heart Rate, Respiration Rate or Skin temperature) exceed the configured limits.

- ***LifeSignals Web UI / Remote Monitoring dashboard*** is a web-browser User Interface Application that enable caregiver (Clinical personnel) to login to the LifeSignals Secure server remotely and access the patient physiological data (Biosensor & derived data) & Alert status. The caregiver (Clinical personnel) depending on the roles (normal or supervisory) can access multiple patient data and search them based on the recent alert status. This includes patients that are active (wearing Biosensor) and procedures completed.

Remote Monitoring Dashboard/Web UI shall also have an ability to continuously display physiological parameters (Heart Rate, Respiration Rate, Skin Temperature, Posture) & waveforms (ECG & Respiration) of multiple patients or single patient quasi-real time remotely on the screen for monitoring by caregiver (Clinical personnel).

This monitoring dashboard also has the ability for the caregiver (clinical personnel) to set the alert limits & notify address that configures the Secure server to send an alert notification to any Mobile Phone (SMS or WhatsApp) or Email ID of care giver, when parameters falls outside the set value.

***Note**:* The Biosensor data may be accessible by a Third-Party Application installed in the Relay device using the Application Programming Interface (API) layer of the LifeSignal Relay Application Software, after suitable configuration and verification. In this configuration, LifeSignals Secure Server is optional and the data from Relay device shall be transmitted to a third-party server location. But the third-party server shall be installed with LifeSignals "*Sensor Processing Library*" for derivation Heart Rate, Respiration Rate, Skin Temperature & Posture.

8 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 display multiple patient physiological data for remote monitoring.

9 Substantial Equivalence comparison (Subject device & Predicate Device)

Comparison	Predicate (K163453)	Subject Device (K202868)
Manufacturer	Vital Connect, Inc. USA	LifeSignals, Inc., USA
Product Codes	DRG (Primary) , DSI , MHX	DRG (Primary), MHX, FLL
Regulation Classification (Primary)	21 CFR 870.2910 Class II	21 CFR 870.2910 Class II
Intended use / Indications 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 data from the Vital Connect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment.	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 falls outside the set limits and to display multiple patient physiological data for remote monitoring.
Intended Population	General care patients who are 18 years or older	Non-critical, adult population, 18 years or older
Intended Use Environment	Home & Healthcare settings	Home & Healthcare settings
Monitored Parameters		
ECG	✓ (Single channel)	✓ (Two channels)
Heart Rate	✓	✓

Comparison	Predicate (K163453)	Subject Device (K202868)
Heart Rate Variability	✓	×
Respiration	✓	✓
Skin Temperature	✓	✓
Posture	✓	✓
Activity	✓	×
Continuous Physiological data monitoring	✓	✓
Heart Rate Range & accuracy (Stationary and Ambulatory**)**	30 – 200 BPM (Range) ± 5 or 10% whichever is greater	30 – 250 BPM (Range) ± 3 or 10% whichever is greater
Respiration Rate Range & accuracy	• 10-30 Breaths per Minute with a mean absolute error of less than 3 Breaths per Minute, validated by clinical studies. • 4-42 Breaths per Minute with a mean absolute error of less than 1.5 Breaths per Minute, validated by simulation studies	• 9-30 Breaths per Minute with a mean absolute error of less than 3 Breaths per Minute, validated by clinical studies. • 6-60 Breaths per Minute with a mean absolute error of less than 1 Breaths per Minute, validated by simulation studies
Skin Temperature Range & Accuracy (Laboratory)	15°C - 50°C (≤ ± 0.3°C) Continuous measurement	32°C - 43°C (Accuracy as per ASTM E1112-00) Continuous measurement
Posture Detection	Lying down, Upright, Walking, Running, or Leaning	Lying down, Upright or Inclined
Programmable Alert Notification & Setting	✓	✓
"Alarm" Function (to assist clinician for immediate intervention)	×	×
Sensor		
Single Use	✓	✓
Wear Life	120 hours	120 hours
Data can be transferred & Stored	✓	✓
Battery	Coin cell – Zinc Air (1 no)	Li-MnO2 (Primary)
Applied part category	Type BF	Type CF
Communication protocol	Bluetooth (BT4.1)	WLAN (802.11b)
Wireless Radio Frequency	2.4 – 2.5 GHz	2.4 - 2.4835 GHz
Communication Security	AES-CCM 128	WPA2-PSK (AES 128)

Comparison	Predicate (K163453)	Subject Device (K202868)
Relay Device		
Authentication from Server	✓	✓
Data transferred to Server	✓	✓
Data buffered if there is no connection with Server	✓	✓
Data accessible from Relay device by 3rd party via API	✓	✓
Secure Server	Data is stored for access by 3rd party software	Data is stored for access by 3rd party software

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

Differences and Risks associated with that:

- Predicate device has only one channel of ECG, whereas the proposed device has two channels of ECG. Additional ECG channel does not add any risk to the device.
- The Predicate device has additional monitoring parameters (Heart Rate variability & Activity) compared to the proposed device. However, these parameters are not required for the claimed intended use of the proposed device.
- The Predicate device has single Zinc-Air battery, whereas the Proposed device has one Li-MnO2 battery (Primary). This change in battery chemistry does not add any risk to the device. Li-MnO2 batteries are commonly used in Wearable Medical devices & tested for safety.
- The Predicate device uses BLE for wireless communication, whereas the Proposed device uses WLAN for wireless communication. The use of WLAN for wireless communication does not add any risk to the device.
- The Applied Part classification of the Predicate device is “BF”, whereas the Proposed device Applied Part classification is “CF”. Devices with CF classified Applied Part has a lower risk with lower leakage current.
- The Subject device has ability to display multiple patient data using a UI interface (Remote Monitoring Dashboard), while the predicate device does not have the ability. However, this does not add any risk, as this function / feature of predicate device is covered under separate 510(k) clearance (K170973). Please refer section 5.10 for further details.

10 Substantial Equivalence comparison Remote Monitoring Dashboard (one of the components of the Subject device) and Reference device I

Comparison	Reference Device – I (K170973)	Subject Device (K202868)
Manufacturer	Vital Connect, Inc., USA	LifeSignals, Inc., USA
Product Codes	DRG	DRG (Primary), MHX
Regulation Classification	21 CFR 870.2910 Class II	21 CFR 870.2910 Class II
Intended use / Indications for use	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.	The LifeSignals Multi-Parameter Remote Monitoring Patch Platform (LX1550) 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 display multiple patient physiological data for remote monitoring.**

Comparison	Reference Device – I (K170973)	Subject Device (K202868)
Physiological Data Monitored	Electrocardiography (ECG), Heart Rate, Heart rate variability, R-R Interval, Respiration rate, skin temperature, activity (including step count) and posture	Electrocardiography (2-channel ECG), Heart Rate, Respiration Rate, Skin Temperature & Posture.
Principles of Operations	Display of data from validated Relay device using third-party developed Graphical User Interface, or VitalWatch, and optional transmission of data to Secure Server.	Display of data from validated Secure server installed with LifeSignals Secure Server Application on any web-based browser using LifeSignals Remote Monitoring Dashboard or any third-party developed GUI.

Note : ✓ - Feature is identical ✗ - Feature not available.

Differences and Risks associated with that :

- Predicate device has only one channel of ECG, whereas the proposed device has two channels of ECG. Additional ECG channel does not add any risk to the device.
- The Predicate device has additional monitoring parameters (Heart Rate variability, R-R variability & Activity) compared to the proposed device. However, these parameters are not required for the claimed intended use of the proposed device.
- In predicate device the display of data is from the validated relay device, while in the subject device the display of data is from the Secure Server. This allows either single or multiple patients data can be displayed on a standard desktop PC or tablet using web-based browser. This does not add any risk.

11 Comparison of previously cleared LifeSignals ECG Remote Monitoring Platform (Reference Device – II)

The LifeSignals Multi-parameter Remote Monitoring Platform is technologically identical to 510(k) cleared LifeSignals ECG remote monitoring Patch Platform with additional monitoring parameters & Remote Monitoring Dashboard

Comparison	Reference Device II (K200690)	Subject Device (K202868)
Manufacturer	LifeSignals, Inc., USA	LifeSignals, Inc., USA
Product Codes	DRG (Primary), MWJ	DRG (Primary), MHX, FLL
Regulation Classification (Primary)	21 CFR 870.2910 Class II	21 CFR 870.2910 Class II
Intended use / Indications for use	The LifeSignals ECG Remote Monitoring Patch Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of Electrocardiography (ECG) & Heart Rate monitoring in home and healthcare settings. Data is transmitted wirelessly from LifeSignals Biosensor to Remote secure server for storage and analysis. The LifeSignals ECG Remote Monitoring Patch Platform includes an ability to notify healthcare professionals when Heart Rate falls outside the set limits	The LifeSignals Multi-Parameter Remote Monitoring Platform (LX1550) 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 display multiple patient physiological data in for remote monitoring.
Intended Population	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
Monitored Parameters		
ECG	✓ (Two channel)	✓ (Two channels)
Heart Rate	✓	✓
Respiration	×	✓
Skin Temperature	×	✓
Posture	×	✓

Comparison	Reference Device II (K200690)	Subject Device (K202868)
Sensor		
ECG Electrodes	Gel & Ag/AgCl Eyelet (Four)	Gel & Ag/AgCl Eyelet (Four)
Temperature sensing	×	Thermistor
Accelerometer	×	3-axis
Dimension Width Length Thickness	 112.0 mm 79.0 mm 6.0 mm	 105.0 mm 94.0 mm 12.0 mm
Weight	18 grams	28 grams
Electrode Distance ECG-A (Diagonal) ECG-B (Vertical)	 60.0 mm 42.4 mm	 90.0 mm 57.9 mm
Location of Body	Upper Left Chest	Upper Left Chest
Sensor & wireless Chip	Life Signal LC1110 (custom chip)	Life Signal LC1110 (custom chip)
Battery	Zinc Air – 2 no – DC 2.8V	Li-MnO2 (1 no)
PCBA	Rigid - Flex	Rigid – Flex
Top cover	Thermoformed Foam	Thermoformed Foam
User inputs	Switch & LED	Switch & LED
Body Contact Material		
Adhesive	Hydrocolloid	Acrylate
Electrode design	Ag/AgCl Eyelet	Ag/AgCl Eyelet
Electrolyte	Hydrogel	Hydrogel
Wear Life	72 hours	120 hours
Electrical (Applied Part)	Type CF – Defib. proof	Type CF – Defib. proof
Single Use	✓	✓
Wear Life	72 hours	120 hours
Data temporary buffered	✓	✓
Battery	Coin cell – Zinc Air (2 nos)	Li-MnO2 (Primary)
Applied part category	Type CF	Type CF
Communication protocol	WLAN (802.11b)	WLAN (802.11b)
Wireless Radio Frequency	2.4 - 2.4835 GHz	2.4 - 2.4835 GHz
Communication Security	WPA2-PSK (AES 128)	WPA2-PSK (AES 128)
Relay Device		
Authentication from Server	✓	✓
Data transferred to Server	✓	✓
Data buffered if there is no connection with Server	✓	✓

Comparison	Reference Device II (K200690)	Subject Device (K202868)
Data accessible from Relay device by 3rd party via API	✓	✓
Secure Server	Data is stored for access by 3rd party software	Data is stored for access by 3rd party software

Note : ✓ - Feature is identical ✖ - Feature not available

Differences and Risks associated with that:

- The distance between electrodes of the Subject Device is different from the Reference Device-II and this may result in clinically significant differences in the acquired ECG signal. However, the increase in electrode distance reduces the risk. Increase in electrode distance substantially increases amplitude of QRS & P-wave amplitude and it helps 3rd party arrhythmia analysis software in improving the detection of arrhythmia.

- Differences in the locations of the electrodes between Subject device & Reference Device-II may result in differences in the electrode placement on patients from a physiological perspective. However, the increase in the electrode distance have not substantially changed the overall dimension that could affect the intended location of the Biosensor (upper left chest). Further the Subject Device has improved design that allows the electrodes to move or flex independently compared to the Reference Device, that helps for better wearability, motion performance and increased wear-period (ability to withstand higher shear stress), which is confirmed through wear-period clinical performance study.

12 Summary of Performance Testing

Verification & Validation activities were performed on LifeSignals Multi-parameter Remote Monitoring Platform to demonstrate substantial equivalence to the predicate device:

- Biocompatibility testing of In-vitro cytotoxicity, skin irritation, Intracutaneous reactivity and skin sensitization were conducted on the LifeSignals Multi-parameter Biosensor Patch, according to *ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1 : Evaluation and Testing within a Risk Management Process*.

- Electrical Safety and electromagnetic compatibility testing were conducted on the Multi-parameter Biosensor Patch for compliance with *ANSI AAMI ES60601-1:2005, ANSI AAMI IEC 60601-1-2:2014* and *ANSI AAMI HA 60601-1-11:2015*.

- ECG Performance testing were repeated on the LifeSignals Multi-parameter Remote Monitoring Platform for compliance with *ANSI AAMI IEC 60601-2-47:2012, IEC 60601-2-27:2011 & ANSI AAMI ISO 60601-2-25:2011*.

- Usability study was conducted on the LifeSignals Multi-parameter Remote Monitoring Platform for compliance with *IEC 60601-1-6:2013* and *"USFDA Guidance- Applying Human Factors and Usability Engineering to Medical Devices.* "

- Wear-life performance of ECG waveform quality, Heart Rate, Respiration Rate & Skin Temperature of LifeSignals Multi-parameter Remote Monitoring Patch Platform under normal use condition was validated using non-randomized, self-control comparative on-body comparative performance study for the wear period of 120 hours.

- ECG & Heart Rate accuracy performance validation of LifeSignals ECG Remote Monitoring Patch Platform (Reference Device-II) under various conditions (normally activity, posture, etc.) using non-randomized, self-control comparative on-body comparative performance, is valid for LifeSignals Multiparameter Remote Monitoring Platform.

- Respiration Rate performance under various postures & normal activity is validated through on-body comparative performance under spontaneous breathing & metronome breathing conditions and also by using bench testing.

- Skin temperature accuracy performance of LifeSignals Multi-parameter Remote Monitoring Patch Platform was verified by using bench testing.

- Wireless performance & coexistence testing conducted as per *ANSI/IEEE C63.27:2017 : American National Standard for Evaluation of Wireless coexistence* on LifeSignals ECG Remote Monitoring Platform (Reference Device-II) is valid for Lifesignals Multiparameter Remote Monitoring Platform as both the Biosensors are based on LifeSignals proprietary Semiconductor platform which is integrated with multi-sensor subsystem, signal processor subsystem and a multiband radio subsystem into a single chip.

- Software in the ECG Remote Monitoring Platform 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" level of concern.

- Shelf-life, Reliability and packaging transportation testing were conducted and verified on LifeSignals Multi-parameter Remote Monitoring Biosensor as per the acceptance criteria.

13 Conclusion

The LifeSignals Multi-parameter Remote Monitoring Platform is substantially equivalent with respect to safety and effectiveness to the legally marketed Predicate device for its intended use. Minor differences between LifeSignals Multi-parameter Remote Monitoring Platform and the predicate device & Reference devices have no significant effect on safety or effectiveness, as established through various performance tests. Further, LifeSignals Multi-parameter Biosensor used in LifeSignals Multi-parameter Remote Monitoring Platform is substantially equivalent with respect to technology & design to the legally marketed Reference Device.