July 15, 2020

LifeSignals, Inc.
Saravanan Balasubramanian
Vice President - Medical Systems & Regulatory Affairs
39355 California Street, Suite 305
Fremont, California 94538

Re: K200690
Trade/Device Name: Life Signal ECG Remote Monitoring Patch Platform
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, MWJ
Dated: June 11, 2020
Received: June 17, 2020

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 (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)*
K200690

Device Name

LifeSignals ECG Remote Monitoring Patch Platform

Indications for Use *(Describe)*

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) and Heart Rate monitoring in home and healthcare settings. Data is transmitted wirelessly from LifeSignals Biosensor Patch to Remote Secure Server for storage and analysis.

The LifeSignals ECG Remote Monitoring Patch Platform is intended for non-critical, adult population, who are 18 years of age or older.

The LifeSignals ECG Remote Monitoring Patch Platform includes an ability to notify healthcare professionals when Heart Rate falls outside the set limits.

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 ECG Remote Monitoring Patch Platform

5.1 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

5.2 Date prepared: July 15, 2020

5.3 Device

Trade Name : LifeSignals ECG Remote Monitoring Patch Platform
Model Name : ECG Remote Monitoring Patch Platform
Common Name : Wireless ECG Remote Monitoring System

5.4 Classification Product code

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

5.5 Subsequent Product codes

Device Panel	Regulation Classification	Product Code	Description
Cardiovascular	21 CFR 870.200 Class II	MWJ	Medical Magnetic Tape Recorder

5.6 Predicate & Reference Devices

Predicate Device :

510(k) Number	: K152139
Model	: Vital Connect Platform
Manufacturer	: Vital Connect, Inc., USA

Reference Device – I (for technology comparison of Biosensor Patch) :

510(k) Number	: K172011
Model	: LifeSignals' WiPoint Biosensor iOS Receiver App System
Manufacturer	: LifeSignals, Inc., USA

Reference Device – II (for ECG data acquisition - Secondary product code MWJ):

510(k) Number	: K152626
Model	: H3+ Holter Recorder
Manufacturer	: Mortara Instrument, Inc.

5.7 Device description

LifeSignals ECG Remote Monitoring Patch Platform consists of three main components: (1) *LifeSignals Biosensor Patch,* (2) *LifeSignals Relay device,* (3) *LifeSignals Remote Secure Server.*

- *LifeSignals Biosensor Patch* acquires ECG signals from the body, pre-processes as two channels of ECG data and are wirelessly transmitted to the Relay device. Under normal operation, when the Relay Device is available within the wireless range, the acquired data is continuously transmitted to the Relay device immediately. If the Relay device is not available or if there is any interruption in the communication between the Relay device and the Biosensor Patch, data shall be buffered (stored) locally in the Biosensor Patch until 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 compatible commercial hardware platform, like a mobile phone or a tablet.

- *LifeSignals Relay Application's* functions:
  - Manage secured wireless communication (WLAN 802.11b) between Relay device and Biosensor Patch and encrypts communication between the Relay device and the LifeSignals Remote Secure Server.
  - Receive ECG signals from the Biosensor Patch and transmit them after encryption to Secure Server as quickly as possible. They manage the database in Relay device, for buffering/storing the data securely if there is any disruption in communication with the Secure Server.
  - Provide user interface for selecting, pairing and establishing connection with Biosensor Patch.
  - Display alert notifications received from the Secure Server when the Heart Rate of its associated Biosensor or of some other Biosensor in its network falls outside the configured range, when it is configured by the Secure Server to receive such notification.

- *LifeSignals Secure Server* consists of a hardware platform that is a Linux-compatible Secure server, LifeSignals Secure Server Application software that is installed in the hardware platform along with a Web UI, a browser-based application that interfaces with LifeSignals Secure Server Application.

  LifeSignals Secure Server Application manages the decryption, uploading and storage of Biosensor data received from multiple authenticated Relay devices. The Signal Processing and Heart Rate Library in the LifeSignals Secure Server Application processes and filters the received ECG signals before storing them in a secured location. It also derives the Heart Rate from the ECG data and the Heart Rate value is appended to the filtered ECG Signals.

  LifeSignals Secure Server Application can include the ability to send alert notifications to any configured Relay Device connected in its network, when Heart Rate value of any Biosensor falls outside the set range of values.

  Web UI provides user interface for user (login) management, Relay management & Heart Rate Alert setting. It interfaces with Secure Server Application.

- The Secure Sever Application does not carry out any arrhythmia analysis of ECG data by itself. However, the ECG data received and stored by the LifeSignals Secure server is intended to be used with an approved third-party ECG analysis software. Based on the type of ECG analysis software, the LifeSignals ECG Remote Monitoring Platform can be used for a suitable clinical workflow such as a Remote Patient Monitoring, Mobile Cardiac Telemetry, Cardiac Event Monitor or Holter Monitoring system.

- The ECG data may be accessible by a Third-Party Application installed in the Relay device using the Application Programming Interface (API) layer of the 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 server location configured by the third-party application. Also, in this configuration, Signal processing and Heart Rate processing Library shall be integrated in third-party secure server application or in third-party relay application.

5.8 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) and Heart Rate monitoring in home and healthcare settings. Data is transmitted wirelessly from LifeSignals Biosensor Patch to Remote secure server for storage and analysis.

The LifeSignals ECG Remote Monitoring Patch Platform is intended for non-critical, adult population, who are 18 years of age or older.

The LifeSignals ECG Remote Monitoring Patch Platform includes an ability to notify healthcare professionals when Heart Rate falls outside the set limits.

5.9 Substantial Equivalence comparison (Subject device & Predicate Device)

Comparison	Predicate (K152139)	Subject Device (K200690)
Manufacturer	Vital Connect, Inc. USA	LifeSignals, Inc., USA
Product Codes	DRG (Primary) , DSI , MHX	DRG (Primary), MWJ
Regulation Classification (Primary)	21 CFR 870.1025 Class II	21 CFR 870.1025 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 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.

Comparison	Predicate (K152139)	Subject Device (K200690)
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	✓	✓
Heart Rate Variability	✓	×
Respiration	✓	×
Skin Temperature	✓	×
Activity & posture	✓	×
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
Programmable Alert Notification & Setting	✓	✓
"Alarm" Function (to assist clinician for immediate intervention)	×	×
Sensor		
Single Use	✓	✓
Wear Life	72 hours	72 hours
Data can be transferred & Stored	✓	✓
Battery	Coin cell – Zinc Air (1 no)	Coin cell - Zinc Air (2 no)
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)
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 any 3rd party software	Data is stored for access by any 3rd party software

Comparison	Predicate (K152139)	Subject Device (K200690)
ECG analysis	No in-built arrhythmia analysis function and is intended to be used by any 3rd party arrhythmia analysis software	No in-built arrhythmia analysis function and is intended to be used by any 3rd party arrhythmia analysis software

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 (Respiration rate, temperature, HR variability) 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 two Zin-Air battery. Additional Battery does not add any risk to the device.
- 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 as it is intended for direct Cardiac Application.

5.10 Technological Characteristics of Biosensor Patch (Subject Device & Reference Device – I)

The LifeSignals Biosensor Patch used in LifeSignals ECG Remote Monitoring Patch Platform is identical to the Biosensor Patch that is used in LifeSignals WiPoint Biosensor iOS Receiver App System, which is 510(k) cleared under K172011, except for firmware change to support different intended use and for additional memory to buffer the data in the Biosensor Patch, as explained in the following table :

Comparison	Reference Device – I (K172011)	Subject Device (K200690)
Manufacturer	LifeSignals, Inc.	LifeSignals, Inc.
Product Code	DRG (Primary), DRT, DRX	DRG (Primary), MWJ
General		
Number of ECG Electrodes	Four Electrodes	Identical
Dimension (L x W x T)	112 x 79 x 6 mm	Identical
Weight	18 grams	Identical

Comparison	Reference Device – I (K172011)	Subject Device (K200690)
Sensor & wireless Chip	Life Signal LC1110 (custom chip)	Identical
Battery	Zinc Air – 2 no – DC 2.8V	Identical
PCBA	Rigid - Flex	Minor change Note1
Top cover	Thermoformed Foam	Identical
User inputs	Switch & LED	Identical
Body Contact Material		
Adhesive	Hydrocolloid	Identical
Electrode design	Ag/AgCl Eyelet	Identical
Electrolyte	Hydrogel	Identical Note2
Wear Life	72 hours	Identical
Electrical (Applied Part)	Type CF – Defibrillation proof	Identical
Wireless Communication		
Protocol	WLAN-802.11b	Identical
Security	WPA2-PSK (AES 128)	Identical

Note 1 : The Firmware & Memory chip are different from the Reference device-I to support the new intended use.
Note 2 : Hydrogel part number is different. It is of same family & manufacturer. (Biocompatibility test is repeated)

5.11 Substantial Equivalence comparison ECG data acquisition performance – Secondary product code (Subject device & Reference Device – II)

Comparison	Reference Device – II (K152626)	Subject Device (K200690)
Manufacturer	Mortara Instrument, Inc., USA	LifeSignals, Inc., USA
Product Codes	MWJ	DRG (Primary), MWJ
Regulation Classification (All product codes)	21 CFR 870.2800 Class II	21 CFR 870.1025 21 CFR 870.2800 Class II
Intended use / Indications for use	The H3+ Holter recorder is intended to acquire, record and store continuous ECG data as directed by a clinician from adult, adolescent, pediatric, infant and neonate patient populations for a maximum recording time of 14 days in a hospital, clinic or home environment. The H3+ is intended to be used with a compatible ambulatory ECG (Holter) analysis system which will analyze the recorded data. The H3+ data and the data analysis are then reviewed by trained medical personnel for the purpose of forming a clinical diagnosis. The H3+ Holter Recorder is not a life-supporting device.	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.
Intended Population	Adult, adolescent, pediatric, Infant & Neonate Patient population	Non-critical, adult population, 18 years or older

Comparison	Reference Device – II (K152626)	Subject Device (K200690)
Intended Use Environment	Home & Healthcare settings	Home & Healthcare settings
Data type	Digital	Digital
Record Duration	Up to 14 days	Up to 72 hours in Biosensor patch, when Relay device is not available in wireless range & in Secure Server when Relay device is available.
Record Medium	Internal Flash Memory	Internal Flash Memory (Biosensor) or Hard disk (Secure Server)
Data Transfer Method	Via USB Port	Wireless
ECG Channels	3	2
Frequency Response	Meets the requirement of IEC 60601-2-47	Meets the requirements of IEC 60601-2-47
Sampling Rate	180 sps	244.14 sps
Dynamic Range	12-bit	16-bit / ± 300 mV
Amplitude Resolution	6.25 uV	5.3 uV
Cable	5-wires	Integrated Patch design
Impedance measurement	No	No
Pacemaker Detection	Yes	No
Time displayed	Yes	Yes (In Relay device)
Dimension	64 x 25 x 19 mm	112 x 79 x 6 mm
Weight	28 grams	18 grams
ECG analysis	No in-built arrhythmia analysis function and is intended to be used with a compatible analysis software	No in-built arrhythmia analysis function and is intended to be used with a compatible analysis software

Differences and Risks associated with that :

- Reference device has three channels of ECG, whereas the proposed device has two channels of ECG.
- Reference device uses 5-wires electrodes, while the proposed device has integrated patch design with four electrodes.
- Reference device is intended for 14 days of recording, while the proposed device is intended for 72 hours. The recording period of more than 48 hours shall be considered to be extended cardiac monitoring. However, if there is a clinical requirement, multiple biosensor Patch can be worn by the patient to extend the monitoring period up to 14 days and the secure sever has ability to record more than 14 days of data simultaneously.
- Reference device has a pacemaker detection capability, while the proposed device does not have pacemaker detection capability. The proposed device is contraindicated for use with active implantable medical devices including pacemakers.

5.12 Summary of Performance Testing

Verification & Validation activities were performed on LifeSignals ECG Remote Monitoring Patch Platform to demonstrate substantial equivalence to the predicate device:

- Biocompatibility testing of In-vitro cytotoxicity, skin irritation and skin sensitization were conducted on the LifeSignals 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 Biosensor Patch for compliance with *IEC 60601-1, IEC 60601-1-2* and *IEC 60601-1-11*.

- Performance testing were conducted on the LifeSignals ECG Remote Monitoring Platform for compliance with *IEC 60601-2-47 and IEC 60601-2-27*.

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

- Ambulatory performance of Heart Rate algorithm and ECG waveform quality of LifeSignals ECG Remote Monitoring Patch Platform was verified using non-randomized, self-control comparative on-body comparative performance study. The adhesion (Wear-life) of LifeSignals Biosensor Patch was also verified in accordance to *AAMI ANSI EC12.*

- Wireless performance & coexistence testing was conducted as per *ANSI/IEEE C63.27:2017 : American National Standard for Evaluation of Wireless coexistence*. Also tested for compliance to *FCC CFR47 Part 15 subpart C & ETSI EN 300 328*

- 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 and packaging transportation testing were conducted and verified as per the acceptance criteria

5.13 Conclusion

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