June 12, 2019

BraveHeart Wireless, Inc.
℅ Thomas Schorre
Official Correspondent
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 444
Ludlum, Florida 33155-3708

Re: K191331
Trade/Device Name: Life Sensor Cardiac Monitor
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG, DRT, DRX
Dated: May 14, 2019
Received: May 16, 2019

Dear Thomas Schorre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Nicole Goodsell
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)*

K191331

Device Name
Life Sensor Cardiac Monitor

Indications for Use *(Describe)*

The Life Sensor Cardiac Monitor (CM) is a wireless monitoring system intended for use by healthcare professionals for monitoring of physiological data within healthcare settings. This includes heart rate and electrocardiography (ECG). Data is transmitted wirelessly from Life Sensor Electrode to an application on iOS device where it is displayed for review by healthcare professionals. The device is intended for use on general care patients 18 years or older and by prescription only.

The device is contraindicated for use on critical care patients, patients with active implantable medical devices such as pacemakers, implanted cardioverter defibrillator (ICD), and left ventricular assist devices (LVAD); for use in magnetic resonance (MR) environments; for use during surgical procedures when electro-surgical equipment is optional. The Life Sensor Cardiac Monitor does not detect or diagnose medical conditions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5

510(k) Summary for Life Sensor Platform

(As required by 21 CFR 807.92)

I. Submitter Information

Submitter	BraveHeart Wireless, Inc. 11 Perimeter Road Nashua, NH 03063
Contact Person:	Balaji Sudabattula VP, Quality and Regulatory Affairs Phone: 385-988-0625 Email: balaji.sudabattula@braveheart.life

Date Prepared:	April 10, 2019

II. Device Identification and Classification

Device Trade Name:	Life Sensor Platform
Model Name:	Life Sensor Cardiac Monitor
Common Name:	Wireless Remote Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency
Classification Panel:	Cardiovascular
CRF Section:	870.2910, 870.2300, 870.2360
Device Class:	II
Product Code:	DRG, DRT, DRX

III. Predicate Device

Manufacturer:	Life Signals, Inc
Model Name:	LifeSignals WiPatch & WiApp System
510(k) #:	K172011

This predicate has not been subject to a design-related recall.

IV. Device Description

Life Sensor Electrode Bluetooth iPad installed with Life Sensor App

The Life Sensor Cardiac Monitor (CM) Platform is a wireless data collection system that monitors physiological data (electrocardiograph and heart rate) and consists of the following sub-systems:

Life Sensor Electrode (includes **Life Sensor Patch** and **Life Sensor Module**)
Life Sensor Firmware
Life Sensor Application

Life Sensor Electrode

- **Life Sensor Patch**: The Life Sensor Patch is the single-use, self-adhesive interface to a patient that is attached to the patient's upper torso region just above the heart.
- **Life Sensor Module**: The Life Sensor Module attached to the Life Sensor Patch, contains the battery powered electronics and sensing apparatus necessary to operate the system. The Life Sensor Module automatically performs all the processing functions related to capturing the required physiological data from the body and performs encrypted, bi-directional communication to the Life Sensor Application, using Bluetooth Low Energy (BLE), when in range of the Life Sensor Application installed on a paired iOS device.
- **Life Sensor Firmware**:
  The Life Sensor Firmware is the software installed on the Life Sensor Module. The Life Sensor Firmware manages bi-directional communication between the Life Sensor Module and the Life Sensor Application. Encrypted data is transmitted to and from the Life Sensor Module and the Life Sensor Application.
- **Life Sensor Application**: The Life Sensor Application, installed on a paired iOS device, interacts with the Life Sensor Firmware and manages the upload, processing, and display of the physiological data transmitted by the Life Sensor Module.
  When installed on a compatible hardware, the Life Sensor Application establishes connection to any of the Life Sensor Electrode through pairing process.

Life Sensor Application has visual alarms to alert clinical personnel when heart rate of the person being monitored is outside the set limits, lead off, asystole, tachycardia and bradycardia, when the battery is low, or when there is loss of communication between the Life Sensor Application and the Life Sensor Electrode.

V. Indications for Use

The Life Sensor Cardiac Monitor (CM) is a wireless monitoring system intended for use by healthcare professionals for monitoring of physiological data within healthcare settings. This includes heart rate and electrocardiography (ECG). Data is transmitted wirelessly from Life Sensor Electrode to an application on iOS device where it is displayed for review by healthcare professionals. The device is intended for use on general care patients 18 years or older and by prescription only.

The device is contraindicated for use on critical care patients, patients with active implantable medical devices such as pacemakers, implanted cardioverter defibrillator (ICD), and left ventricular assist devices (LVAD); for use in magnetic resonance (MR) environments; for use during surgical procedures when electro-surgical equipment is optional. The Life Sensor Cardiac Monitor does not detect or diagnose medical conditions.

VI. Summary Table of Substantial Equivalence

Comparison	**Life Sensor Platform (subject)**	**WiPatch & WiApp System**
Sponsor	BraveHeart Wireless, Inc. Nashua, NH	LifeSignals Fremont, CA
Intended use	The Life Sensor Platform is a wireless monitoring system intended for use by healthcare professionals for surveillance of physiological data within healthcare settings. This includes heart rate and electrocardiography (ECG). Data is transmitted wirelessly from Life Sensor Patch to an application on iOS device where it is displayed for review by healthcare professionals. The device is intended for use on general care	The LifeSignals WiPatch & WiApp system is intended for spot check and short-term monitoring of ECG & heart rate of patients at rest or patients who can be transported within the range of the antenna network. The WiPatch & WiApp system has visual and audio alarms to alert clinical personnel when heart rate falls outside the set limits. The device is intended for use on general care patients of 18 years or older. The device is not intended for

Comparison	Life Sensor Platform (subject)	WiPatch & WiApp System
	patients 18 years or older and by prescription only.	use on critical care patients.
Intended Population	Adults ≥ 18	Adults ≥ 18
Intended Use Environment	Healthcare facility	Healthcare facility
Heart Rate	Yes	Yes
ECG Display	Single channel	ECG-A and ECG-B
Sensor	Wireless patch design – RF/Bluetooth 2.4 GHz	Wireless patch design RF/Wi-Fi 2.4 GHz 802.11b
Wear duration	72 hours maximum	72 hours maximum
Hardware Platform	Standard commercial iOS tablet	Standard commercial iOS tablet
Technical Specifications		
Display Range	30 to 200 BPM	30 to 250 BPM
Accuracy	±10 or ±5/min, whichever is greater.	±3/min
Battery	Lithium ion (non-chargeable)	Two zinc air coin cell batteries

Life Sensor CM Platform and the predicate device (LifeSignals WiPatch & WiApp System, 510(k) #: K172011) monitor and display ECG and heart rate. Healthcare professional can set limits for heart rate to alarm the healthcare provider if a patient's heart rate falls outside the set limits. Both transmit data to an iPad for review by healthcare professional.

Minor difference is that the predicate device uses Wi-Fi while the subject device uses Bluetooth Low Energy (BLE) to communicate with iPad.

VII. Summary of Performance Testing

The following non-clinical testing has been completed to demonstrate safety and effectiveness of the Life Sensor Cardiac Monitor Platform.

- Biocompatibility testing, including in-vitro cytotoxicity, irritation and sensitization, performed according to the recommendations of ISO 10993-1:2018, *Biological evaluation of medical devices – Part: Evaluation and testing*.
- Electrical safety and EMC testing. The device complies with IEC 60601-1, IEC 60601-2-27, IEC 60601-1-2.

- Software verification and validation testing was conducted, and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* The software for this device is determined as "moderate" level of concern because a failure or latent flaw could lead to a minor injury to the patient through incorrect information or through the action of the care provider.
- Bench testing, including shelf life, packaging integrity, operation and storage conditions.
- Usability testing. The device complies with IEC 62366.

VIII. Conclusion

The Life Sensor Cardiac Monitor Platform is substantially equivalent with respect to safety and effectiveness to the legally marketed predicate device for its intended use.