June 14, 2018

LifeSignals, Inc. for HMicro, Inc.
% Saravanan Balasubramanian
Principal Consultant
LifeSignals, Inc.
39355 California St., Ste. 305
Fremont, CA 94538

Re: K172011
Trade/Device Name: LifeSignals WiPoint Biosensor_iOS Receiver_App System (LifeSignals WiPatch & WiApp System)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Codes: DRG, DRX, DRT
Dated: June 1, 2018
Received: June 4, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K172011

Device Name

LifeSignals WiPoint Biosensor_iOS Receiver_App System (LifeSignals WiPatch & WiApp System)

Indications for Use *(Describe)*

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 use on critical care patients.

The LifeSignals WiPatch & WiApp System is contraindicated for use on patients with active implantable medical devices such as pacemakers, implanted cardioverter defibrillator (ICD) & left ventricular assist devices (LVAD); for use in a magnetic resonance (MR) environment; for use during surgical procedures when electro-surgical equipment is operational.

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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"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."

510(k) Summary for
LifeSignals WiPoint Biosensor_iOS Receiver_App System

1. **Company name:** LifeSignals, Inc.

   Contact: Saravanan Balasubramanian, Principal Consultant
   Email: saravanan@lifesignals.com
   Tel: 510.770.6412 Ext. 4

2. **Date prepared:** June 11, 2018

3. **Device**

   Trade Name: LifeSignals WiPoint Biosensor_iOS Receiver_App System
   Model Name: LifeSignals WiPatch & WiApp System
   Common Name: Monitor, cardiac (incl. cardio-tachometer and rate alarm)

4. **Classification**

Device Panel	Regulation Classification	Product Code	Description
Cardiovascular	21 CFR 870.2910 Class II	DRG	RF physiological signal transmitter and receiver
Cardiovascular	21 CFR 870.2360 Class II	DRX	Electrocardiograph electrode
Cardiovascular	21 CFR 870.2300 Class II	DRT	Monitor, cardiac (incl. cardio-tachometer & rate alarm)

5. **Predicate Device**

   Vios Monitoring System (K150992)

6. Intended Use

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 use on critical care patients

The LifeSignals WiPatch & WiApp System is contraindicated for use on patients with active implantable medical devices such as pacemakers, implanted cardioverter defibrillators (ICD) and left ventricular assist devices (LVAD); for use in a magnetic resonance (MR) environment; for use during surgical procedures when electro-surgical equipment is operational.

7. Device description

Figure -1 Illustration of WiPatch and WiApp System

The LifeSignals WiPatch & WiApp System consists of the 1) LifeSignals WiPatch 2) LifeSignals WiApp System and 3) Access Point as described below.

<u>The LifeSignals WiPatch:</u>

- is a wireless ECG patch that--when attached to the upper left chest of a patient--continuously acquires physiological signals and transmits these signals wirelessly to any compatible receiver.
- is disposable and integrated with four adhesive electrodes for body interface.
- acquires two channels of electrocardiograph (ECG-A and ECG-B) signals
- transmits acquired signals after initial pre-processing to a compatible receiver wirelessly using the 802.11b communication protocol (2.4 GHz).

- is powered by two-coin cell batteries (zinc air) with an operating life up to 72 hours.
- has an integrated switch to power it on, and has bi-color LED indicators to indicate the communication status with the receiver.

The LifeSignals WiApp System:

- consists of a LifeSignals WiApp Software App (WiApp SW), and a compatible commercial iOS device (iPad, iPad 2, iPad Air or iPad Air 2)
- software, when installed on a compatible hardware, establishes a connection to any one of the LifeSignals WiPatches connected to the same wireless network/Access Point through a pairing process.
- receives the transmitted signals from the paired WiPatch wirelessly, processes the signals and displays heart rate, ECG (ECG-A and ECG-B) waveforms on its LCD display for monitoring purposes by trained clinical personnel.
- has audio and visual alarms to alert clinical personnel when heart rate of a patient is outside the set limits, lead off, when the battery is low (either the WiPatch or the WiApp System - iPad), or when there is a loss of communication link between the WiApp System and the WiPatch.

Access Point:

An access point is a commercially available hardware device (a.k.a wireless router) that allows wireless capable devices connect through a wireless standard (e.g. 802.11b). LifeSignals WiPatch and WiApp system communicate through an access point.

8. Summary Table of Substantial Equivalence

Table 12-1: Table of Comparison

Comparison	**WiPatch & WiApp System** (Subject)	**VIOS Monitoring System** (Predicate)
510(k)	K172011	K150992
Sponsor	LifeSignals, Inc. Fremont, CA	Vios Medical, Inc. St. Paul, MN

Table 12-1: Table of Comparison

Comparison	WiPatch & WiApp System (Subject)	VIOS Monitoring System (Predicate)
Intended use/Indications for use	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 use on critical care patients.	The Vios Monitoring System (VMS) is intended for use by medically qualified personnel for physiological and vital signs monitoring of adult (18+) patients in healthcare facilities. It is indicated for use in monitoring of ECG, heart rate, pulse rate, functional oxygen saturation of arterial hemoglobin, and axillary temperature.
Intended Population	Adults ≥ 18	Adults ≥ 18
Intended Use Environment	Healthcare facility	Healthcare facility or clinical pharmacological unit
Heart Rate	Yes	Yes
Temperature	No	Yes
ECG Display	ECG-A and ECG-B	Channel I and II
SpO2	No	Optional
Pulse Rate	No	Optional
NiBP	No	Optional
Sensor	Wireless patch design—RF/Wi-Fi 2.4 GHz 802.11b	Wireless patch design—RF/Bluetooth 2.4 GHz
Wear duration	72 hours (maximum)	
Hardware Platform	Standard commercial iOS tablet (iPad, iPad2, iPad Air, iPad Air2)	Standard commercial IT equipment
TECHNICAL SPECIFICATION (HEART RATE)		
Display Range	30 to 250 BPM	
Accuracy	+/- 3 BPM [Note 1]	
Resolution	1 BPM	

Table 12-1: Table of Comparison

Comparison	WiPatch & WiApp System (Subject)	VIOS Monitoring System (Predicate)
ALARMS		
Vital signs parameter	Visual and audio	Visual and audio
Technical alarms – System Low Battery, Patch Low Battery, Lead Off, Connection Lost	Visual and audio	Visual and audio
Power (sensor module)	Two zinc air coin cell batteries	Lithium battery

Note 1:
Heart Rate accuracy on Simulator study is +/- 3 BPM or better for 100% of data.
Heart Rate accuracy on-body performance study is +/- 3 BPM or better for 97% of data

Minor differences are: 1) the predicate device has an ability to display additional parameters, including SpO2 (optional), pulse rate (optional) and temperature, while the subject device (WiPatch & WiApp System) does not support or display these additional parameters - SpO2, pulse rate and temperature; 2) the subject device is battery powered with two zinc air coin cell batteries while the predicate device is powered with a lithium battery.

9. Summary of Performance Testing

The following non-clinical testing has been completed to demonstrate safety and effectiveness of the LifeSignals WiPatch & WiApp System: -

- Bio-compatibility testing per ISO 10993-1, ISO 10993-5 and ISO 10993-10:2003
- Safety and performance testing per IEC 60601-1:2012, AAMI/ANSI/EC 60601-1-2:2007/(R)2012, IEC 60601-2-27:2011, ANSI/AAMI/EC12:2000/r2015, IEC 60601-1-8:2012, 47 CFR 15 FCC Part 15C, and ANSI C63.27:2017
- Battery safety testing as per IEC 60086-5:2016
- Design verification and validation: Software Unit(s) verification and Software System verification & validation as per IEC 62304:2015 / USFDA Guidance-General Principles of Software validation; Wireless performance (QoS); Product Design verification.
- Usability engineering as per IEC 62366:2007 +A1:2014

In addition, performance data for heart rate accuracy and on-body adhesion for determination of wear duration was validated using a non-randomized, self-control comparative clinical study.

10. Conclusion

The LifeSignals WiPoint Biosensor_iOS Receiver_App System (WiPatch & WiApp System) is substantially equivalent with respect to safety and effectiveness to the legally marketed predicate device for its intended use.