April 23, 2018

Isansys Lifecare Ltd
% André Kindsvater
Senior Consultant RA & QA
Emergo Global Consulting, LLC
2500 Bee Cave Road
Austin, Texas 78746

Re: K172329
Trade/Device Name: Patient Status Engine
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: March 26, 2018
Received: March 27, 2018

Dear André Kindsvater:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172329

Device Name
Patient Status Engine

Indications for Use *(Describe)*
The Patient Status Engine is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This includes heart rate, heart rate variability (R-R interval), ECG derived respiration rate data (EDR), skin temperature, activity, posture and optional SpO2 and non-invasive Blood Pressure (BP). Data is transmitted wirelessly from the sensors to the Patient Gateways and from the Patient Gateways to a central Server where it is stored for analysis. The Patient Status Engine can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information.

The data from the Patient Status Engine is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients nor replace standard monitoring and/or routine care.

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
Patient Status Engine

K 172329

1. Submission Sponsor

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3. Date Prepared

July 28, 2017

4. Device Identification

Trade/Proprietary Name:	Patient Status Engine
Common/Usual Name:	Wireless Remote Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulation Number:	870.2910
Product Code:	DRG
Device Class:	Class II
Classification Panel:	Cardiovascular

5. Legally Marketed Predicate Device

K152139 - Vital Connect Platform/VitalPatch/HealthPatch MD by Vital Connect Inc.

6. Device Description

The Patient Status Engine (PSE2) is a wireless data collection system that monitors physiological data and consists of the following components / subsystems and optional third party devices as listed below:

Device Name:	Patient Status Engine
Components and Subsystems:	Patient Gateway (Samsung Tablet) – Manufactured by Samsung Patient Gateway Software – Manufactured by Isansys Lifecare Ltd Lifetouch Blue Sensor – Manufactured by Isansys Lifecare Ltd Lifetemp Sensor– Manufactured by Isansys Lifecare Ltd Lifeguard Server Software – Manufactured by Isansys Lifecare Ltd
Additional third party Accessories:	Pulse Oximeter 3150– Manufactured by Nonin Blood Pressure Monitor UA767– Manufactured by A&D Medical Skintact ECG Electrodes – Manufactured by Leonhard Lang Ambu White Sensors – Manufactured by Ambu Inc.

At the subsystem level the Patient Gateway, Lifetouch Blue Sensor and Lifetemp Sensor are collectively identified as the Patient Digitisation Engine (PDE2). The inclusion of the Lifeguard Server completes the Patient Status Engine (PSE2).

7. Indication for Use Statement

The Patient Status Engine is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This includes heart rate, heart rate variability (R-R interval), ECG derived respiration rate data (EDR), skin temperature, activity, posture and optional SpO2 and non-invasive Blood Pressure (BP). Data is transmitted wirelessly from the sensors to the Patient Gateways and from the Patient Gateways to a central Server where it is stored for analysis. The Patient Status Engine can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information.

The data from the Patient Status Engine is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients nor replace standard monitoring and/or routine care.

8. Substantial Equivalence Discussion

The following table compares the Patient Status Engine to the predicate device with respect to indications for use, principles of operation, technological characteristics, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	Isansys Lifecare Ltd	Vital Connect Inc.	Variances / Equivalence
Trade Name	Patient Status Engine	Vital Connect Platform, Healthpatch MD, VitalPatch	
510(k) Number		K152139	N/A
Product Code	DRG	DRG	Same

Manufacturer	Isansys Lifecare Ltd	Vital Connect Inc.	Variances / Equivalence
Trade Name	Patient Status Engine	Vital Connect Platform, Healthpatch MD, VitalPatch	
Regulation Number and Regulation Name	870.2910 Transmitters and Receivers, Physiological Signal, Radiofrequency	870.2910 Transmitters and Receivers, Physiological Signal, Radiofrequency	Same
Indications for Use	The Patient Status Engine is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This includes heart rate, heart rate variability (R-R interval), ECG derived respiration rate data (EDR), skin temperature, activity, posture and optional SpO2 and non-invasive Blood Pressure (BP).	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).	Equivalent - the differences not affecting safety or effectiveness The Patient Status Engine does not have electrocardiography ECG. The Patient Status Engine does include optional SpO2 and non-invasive Blood Pressure, supplied as optional cleared third party accessories.
	Data is transmitted wirelessly from the sensors to the Patient Gateways and from the Patient Gateways to a central Server where it is stored for analysis	Data are transmitted wirelessly from the Vital Connect Sensor for storage and analysis.	Equivalent
	The Patient Status Engine can include the ability to notify healthcare professionals when physiological data fall outside selected parameters	The Vital Connect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters	Equivalent
	The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological	The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information.	Equivalent

Manufacturer	Isansys Lifecare Ltd	Vital Connect Inc.	Variances / Equivalence
Trade Name	Patient Status Engine	Vital Connect Platform, Healthpatch MD, VitalPatch	
	information.		
	The data from the Patient Status Engine is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients nor replace standard monitoring and/or routine care.	The data from the Vital Connect 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.	Equivalent
Mechanism of Action	Physiological data acquisition (wireless) and display	Physiological data acquisition (wireless) and display	Equivalent
Technology Overview	PEMS and Software, wireless communication	PEMS and Software, wireless communication	Equivalent
Touchscreen with Graphical User Interface	Touchscreen to operate Graphical User Interface (GUI) on the Patient Gateway.	The Software Library is run in third party devices. No other information publicly available.	Equivalent - the differences does not affect safety or effectiveness, as determined by verification and validation testing
Ambulatory monitoring sensors	Yes	Yes	Equivalent
Heart Rate,	Yes	Yes	Equivalent
R-R interval	Yes	Yes	Equivalent - the differences do not affecti safety or effectiveness, as demonstrated by V&V testing.

Manufacturer	Isansys Lifecare Ltd	Vital Connect Inc.	Variances / Equivalence
Trade Name	Patient Status Engine	Vital Connect Platform, Healthpatch MD, VitalPatch	
Electrocardiography (ECG)	No	Yes	Different - The Patient Status Engine does not include ECG in the indications for use and make no claims of such. This does not raise new questions of safety and effectiveness for its intended use.
Respiration Rate,	Yes	Yes	Equivalent – the differences do not affect safety or effectiveness, as demonstrated by V&V testing.
Thermistor Probe to detect skin Temperature	Yes	Yes	Equivalent - the differences do not affect safety or effectiveness, as demonstrated by V&V testing.
Skin Temperature	Yes	Yes	Equivalent - the differences not affecting safety and effectiveness.
Activity	Yes	Yes	Equivalent
Posture	Yes	Yes	Equivalent
SpO2	Yes	No	Different - the Patient Status Engine may be used with an FDA cleared SpO2 oximeter. This is an addition to the indications for use as compared to the predicate, but this has been demonstrated as safe and effectives through V&V testing.

Manufacturer	Isansys Lifecare Ltd	Vital Connect Inc.	Variances / Equivalence
Trade Name	Patient Status Engine	Vital Connect Platform, Healthpatch MD, VitalPatch	
Non-invasive Blood Pressure (BP)	Yes	No	Different - the Patient Status Engine may be used with an FDA cleared BP monitor. This is an addition to the indications for use as compared to the predicate, but this has been demonstrated as safe and effectives through V&V testing.
Sterile	No	No	Equivalent
Single-Use	Yes	Yes	Equivalent
Battery Operated	Yes	Yes	Equivalent - the differences not affecting safety and effectiveness.
AC Powered	No	No	Equivalent
Central Server	Yes	Yes	Equivalent - the difference does not affect safety or effectiveness.. Both servers offer a secure means of managing the upload, processing, storage and display of sensor derived data.
Complies with BS EN ISO 10993-1	Yes	Yes	Equivalent.
Electrical Safety Testing	Yes	Yes	Equivalent.
EMC Testing	Yes.	Yes	Equivalent.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the Patient Status Engine and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Isansys Lifecare Ltd completed a number of non-clinical performance tests against applicable standards.

Table 5B – Performance Standards Testing Summary

Test		Pass / fail criteria	Results
1	Electrical safety	Compliance to BS EN 60601-1:2006+A12:2014	Passed
2	Electromagnetic compatibility	Compliance to BS EN 60601-1-2: 2007	Passed

Test		Pass / fail criteria	Results
3	Homecare environment	Compliance to BS EN 60601-1-11:2010	Passed
4	Electrocardiographic monitoring equipment	Compliance to BS EN 60601-2-27:2014	Passed
5	Biocompatibility	Compliance to BS EN ISO 10993-1:2009	Passed
6	Risk Management	Compliance to BS EN ISO 14971:2012	Passed
7	Software	Compliance to BS EN 62304:2006+A1:2015	Passed
8	Usability	Compliance to BS EN 62366-1:2015	Passed

The Patient Status Engine passed all the testing in accordance with internal requirements, national standards, and international standards to support substantial equivalence of the subject device:

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics, but can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown through the documents provided in this 510(k) submission that the minor differences between the Patient Status Engine and the predicate devices Vital Connect Platform/Healthpatch MD/VitalPatch do not raise any new questions regarding its safety and performance.

The Patient Status Engine has the same intended use and the same or similar indications for use and technological characteristics as the previously cleared predicate device, Vital Connect Platform/Healthpatch MD/VitalPatch.

The Patient Status Engine as designed and manufactured, is determined to be substantially equivalent to the predicate device.