DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 2, 2015

Intelesens Limited
% Mr. Paul Dryden, President
Promedic, Inc.
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

Re: K151027
Trade/Device Name: Zensor System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II (Two)
Product Code: MHX
Dated: August 21, 2015
Received: August 24, 2015

Dear Mr. Dryden:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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 on last page.

510(k) Number *(if known)*

K151027

Device Name

zensor System

Indications for Use *(Describe)*

The zensor monitoring device is a small, lightweight, wearable, non-invasive, re-chargeable battery operated system connected to an electrode accessory (single-use disposable Intelesens zensor Electrode Array) which in turn is in contact with the patient's body.

The device is to be used in the home environment to provide clinicians with patient physiological data.

The zensor monitoring system provides full disclosure ECG and cardiac event monitoring for adult patients.

The zensor monitoring system displays ECG and respiration waveforms from the zensor monitoring device. The system monitors the following configurable physiological parameters: Heart Rate and Respiration Rate, as well as key cardiac arrhythmias, and a patient activated recording.

The zensor monitoring system has the option to store full disclosure ECG, Respiration and accelerometer data and/or wirelessly transmit pre-defined event alerts to the Intelesens zensoronline system for review by healthcare practitioners. All physiological data stored on the device can be imported for viewing on Intelesens zensor+ (Ambulatory Full Disclosure ECG and Event Viewer) for later analysis by a clinician.

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

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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Date Prepared April 13, 2015

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Proprietary or Trade Name: zensor System

Common/Usual Name: Physiological Patient Monitor

Classification Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
MHX, Class II, CFR 870.1025

Predicate Device: Intelesens Aingeal VS-200 K110015

Device Description:

zensor System

Device

The zensor system includes the following components:

- zensor device a wireless (Wi-Fi) monitoring device
- Adherent electrode array

Software

- zensor App for configuration of device settings
- zensoronline web based monitoring application identical to Canberra cleared in K110015 and K131000 except for name change and support of zensor functionality.
- zensor+, full disclosure and event data viewing PC software

The zensor also includes a standalone battery charger.
Charging does not / cannot occur when the zensor device is connected to a patient.

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zensor Device

The zensor device monitors physiological parameters and is a wireless, wearable ECG and respiratory monitor. It is a small, battery-operated system comprised of the zensor monitoring unit (a body worn transmitter device), the zensor electrode array, and zensor battery pack. The zensor device is connected to the electrode array via magnetic studs, and the array is positioned as appropriate on the patient's body. The electrode array consists of three patch electrodes containing conductive gel and is self-adhesive and will adhere to the patient's skin. The zensor device communicates to a remote data base using Wi-Fi or mobile hotspot. The rechargeable battery pack contains a rechargeable 3.7V lithium ion battery to power the zensor device. The battery pack is charged using the zensor single bay charging dock.
When fully charged the life of the battery pack can be up to three days (dependent on device configuration).

The physiological parameters monitored include ECG and respiration waveforms, heart rate and respiration rate, activity, detection of cardiac arrhythmias (Asystole, Tachycardia, Ventricular Fibrillation, Bradycardia and Atrial Fibrillation) and recording of patient-activated events.

The zensor monitoring device has the option to store full disclosure ECG and respiration data and/or wirelessly transmit pre-defined event alerts or patient-activated recordings to the Intelesens zensor online system for review by healthcare practitioners. All physiological data stored on the device can be downloaded for viewing on Intelesens zensor+ (Ambulatory Full Disclosure ECG and Event Viewer) for later analysis by a clinician.

The device also contains on-board ECG arrhythmia detection algorithms to automatically record and send ECG data on detection of one or more of the following arrhythmias:

- asystole,
- ventricular fibrillation, (VF)
- bradycardia
- atrial fibrillation (AF)
- tachycardia

Accelerometer: The zensor device incorporates a digital accelerometer MEMS (Micro Electro Mechanical System). This is used to monitor 3-axis acceleration, providing information on patient activity.

Electrode Array

- The zensor electrode array is a patient worn adhesive sensor that facilitates the acquisition of ECG (3 lead) and respiration signals.
- The array is placed onto the patient following the instructions detailed in the user manual.
- The array consists of three electrodes and 5 magnetic studs for connecting to the device.

zensor electrode array has the same patient contact materials as the V-Patch electrode (K131000)

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Zensor Specifications:

Function/Characteristic	Zensor
ECG/Heart Rate	
Number of leads	3
Sample rate	360 Hz
Bandwidth	0.67 – 40 Hz
Resolution	12-bit
Respiration	
Sample rate	120 Hz
Resolution	12-bit
Accelerometer	
Number of axes	3
Sensitivity	+/-2G
Sample rate	100 Hz
Power	
Battery	Rechargeable Varta 3.7V Li Polymer Battery
Operational life	3 days ECG only full disclosure (less for respiration recording and event transmission)
Physical Properties	
Dimensions	96mm (H) x 71mm (W) x 19mm (D)
Weight	85g
Environmental rating	IP22
Data Transmission	
Type	Wi-Fi 802.11 b/g
Range	50 m

zensor App

The zensor App is used to setup and configure the zensor device. It can be navigated using the tabs to view and configure different elements of zensor, including changing monitoring parameters, backing up and copying recorded data, transferring data to zensor online and accessing both zensor online and zensor+ software analysis tools. It communicates to the host computer via USB. Connection can only be made to the device when it is not connected to the patient.

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Indications for Use:
The zensor monitoring device is a small, lightweight, wearable, non-invasive, re-chargeable battery operated system connected to an electrode accessory (single-use disposable Intelesens zensor Electrode Array) which in turn is in contact with the patient's body.

The device is to be used in the home environment to provide clinicians with patient physiological data.

The zensor monitoring system provides full disclosure ECG and cardiac event monitoring for adult patients.

The zensor monitoring system displays ECG and respiration waveforms from the zensor monitoring device. The system monitors the following configurable physiological parameters: Heart Rate and Respiration Rate, as well as key cardiac arrhythmias, and a patient activated recording.

The zensor monitoring system has the option to store full disclosure ECG, Respiration and accelerometer data and/or wirelessly transmit pre-defined event alerts to the Intelesens zensoronline system for review by healthcare practitioners. All physiological data stored on the device can be imported for viewing on Intelesens zensor+ (Ambulatory Full Disclosure ECG and Event Viewer) for later analysis by a clinician.

Patient Population:
Adult

Environment of Use:
Home environment

Contraindications:
- No contraindications exist

Technology:
The zensor System is an electronic device that contains software. It conforms to the applicable performance requirements contained in and referenced in this 510(k). The zensor System conforms to the following standards:

- AAMI ANSI ES 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).
- AAMI / ANSI EC12:2000/(R) 2005, Disposable ECG electrodes.
- AAMI / ANSI EC57:1998/(R) 2008, Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
- AAMI ANSI IEC 60601-2-47: 2012 particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

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Summary of Performance Data
The zensor System has been tested in accordance with the relevant test plans/reports included with this 510(k) submission using the production equivalent units prior to release to market.

Testing includes:

- Hardware Verification
- Compliance with AAMI ANS ES 60601-1
- Compliance with IEC 60601-1-2
- System Validation
- Compliance with AAMI EC 57
- Compliance with AAMI EC12
- Compliance with AAMI ANSI IEC 60601-2-47
- Compliance with IEC 60601-1-11

Risk analyses identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Intelesens' product development procedure. Intelesens' Quality System conforms to 21CFR820 and is certified by SGS UK Ltd. to ISO13485:2003 and ISO13485:2012.

Substantial Equivalence

Indications –
The indications for use are equivalent.

Prescriptive – The zensor and predicate are both prescription devices.

Design and Technology – The zensor and predicate have equivalent design features and technology

Performance and Specifications – The zensor has equivalent specifications of performance as the predicate.

Patient Population –
The zensor and predicate are indicated for adults

Environment of Use – zensor and predicate includes home

Differences –There are no differences between the proposed device and the predicate device that raise any new safety and efficacy concerns.

Substantial Equivalence Conclusion-
It is Intelesens' opinion that the zensor Monitoring System is substantially equivalent to the predicate device, and is safe and effective.