



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

February 26, 2016

Intelesens, Ltd.
Paul Dryden
Consultant
17 Heron Road
Belfast, BT3 9LE GB

Re: K153275

Trade/Device Name: Aingeal Activity System

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)

Regulatory Class: Class II

Product Code: MHX

Dated: January 28, 2016

Received: January 29, 2016

Dear Paul 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K153275

Device Name
Aingeal Activity System

Indications for Use (Describe)

The Intelesens Aingeal Activity is used to monitor and transmit physiological data to a remote application for display or analysis by a clinician. The device can be worn by ambulatory or non-ambulatory adult patients in a healthcare environment to support clinical staff when they are carrying out their routine observations or when a patient would otherwise be in an unmonitored or unobserved situation.

This re-usable device is intended to be used on the patient for short term periods only.

The device is intended to be used on adult patients for monitoring of ECG, respiration, heart rate, skin temperature and activity levels in a healthcare setting.

The device can be used where information on ECG, respiration, heart rate, skin temperature, and activity levels would be useful.

The device uses on-board ECG arrhythmia detection algorithms to automatically record and send ECG data if the user is suspected to be experiencing an arrhythmia event. The device also detects and records respiration, skin temperature and activity. The device transmits the data to the remote application at user defined intervals or upon the detection of an arrhythmia event (arrhythmia or threshold breach).

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)

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 November 10, 2015

Official Contact: Patricia Pepper
Regulatory Affairs Officer
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Proprietary or Trade Name: Aingeal Activity 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:

Aingeal Activity System

The Aingeal Activity System is a modification of the Intelesens Aingeal (VS200) 510(k) cleared under 510(k) K110015. Details of the modifications can be found in **Section 11**.

The Aingeal Activity system includes the following components:

- Aingeal Activity Monitor a wireless (Wi-Fi) monitoring device with a rechargeable lithium polymer battery
- Adherent electrode array
- Battery charger
- Compatible monitoring software such as CPC Bernoulli (FDA 510(k) clearance # K130208)

The Aingeal Activity device is battery powered. The battery is removed from the device prior to charging in the standalone battery charger station. Charging does not occur when the Aingeal Activity device is connected to a patient. Aingeal Activity is a reusable, non-sterile device to be used with a single use disposable electrode.

The battery is charged in a separate charger, charging does not / cannot occur when the Aingeal Activity Device is connected to a patient

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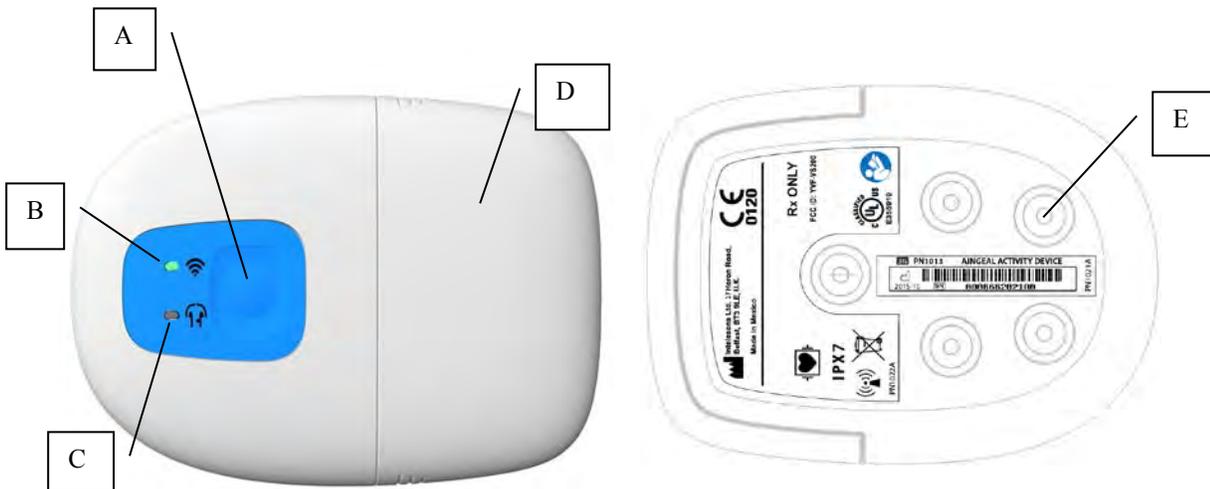
Aingeal Activity Monitor

The Aingeal Activity monitor clips on the adherent electrode array and is worn on-body. In conjunction with the array it collects, stores and transmits user physiological data. The electrode array and device, when enabled and applied to the user's torso will measure ECG, heart rate, respiration rate, skin temperature and activity levels with on board software algorithms. This data is transmitted periodically to the compatible third party server for display such as the CPC Bernoulli software (server). ECG signals recorded by the electrode array and device will also be transmitted on a heart rate trigger basis with thresholds adjustable by the user, or arrhythmia. Respiration signals recorded by the electrode array and device will also be transmitted on a respiration rate trigger basis with thresholds adjustable by the user. Skin temperature is recorded by the electrode array and device will also be transmitted on a temperature level trigger basis with thresholds adjustable by the user. The ECG, respiration signals, skin temperature value and activity metrics are also transmitted periodically and can be displayed via the server.

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

1. asystole,
2. ventricular fibrillation, (VF)
3. bradycardia
4. tachycardia (Ventricular or Supraventricular)

Controls Indicators and Labeling of Aingeal Activity



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Figure 1: Aingeal user interface

A	On/Off button
B	Connection LED: orange or green indicates monitor status
C	Blue LED indicates Leads off or ECG and respiration have not yet been detected.
D	Aingeal Activity battery pack
E	Connecting studs

Table 10.1 Specifications

Function/Characteristic	Intelesens Aingeal Activity
ECG/Heart Rate	
Number of leads	Single
Sample Rate	360 Hz
Bandwidth	40 Hz
Resolution	12 bit
Respiration	
Sample Rate	120 Hz
Resolution	12 bit
Accelerometer	
Number of axes	3
Sensitivity	+/-2G
Sample rate	100 Hz
Skin Surface Temperature	
Accuracy	+ / - 0.2 °C
Range	30 °C to 45 °C
Sample Rate	10 Hz
Power	
Battery	Rechargeable Poliflex 3.7 V Li Polymer battery x1

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Operational Life	24 hours at 1 minute reporting frequency; Longer for less frequent readings
Physical Properties	
Dimensions	96mm (H) x 71mm (W) x 19 mm (D)
Weight	85g
Environmental rating	IPx7
Data Transmission	
Type	Wi-Fi 802.11 b/g
Range	50 m

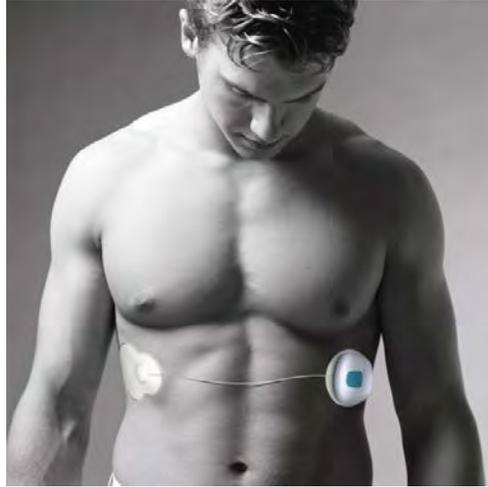
When fully charged the life of the battery pack is 24 hours when set to 1 minute update interval.

Electrode Array:

- The Aingeal Activity electrode array is a patient worn adhesive sensor that facilitates the acquisition of ECG, respiration and temperature measurement.
- The array is placed onto the patient following the instructions detailed in the user manual.
- The array consists of two electrodes and magnetic studs for connecting to the device.

The electrode array has the same patient contact materials as the zensor electrode array cleared under 510(k) K151027

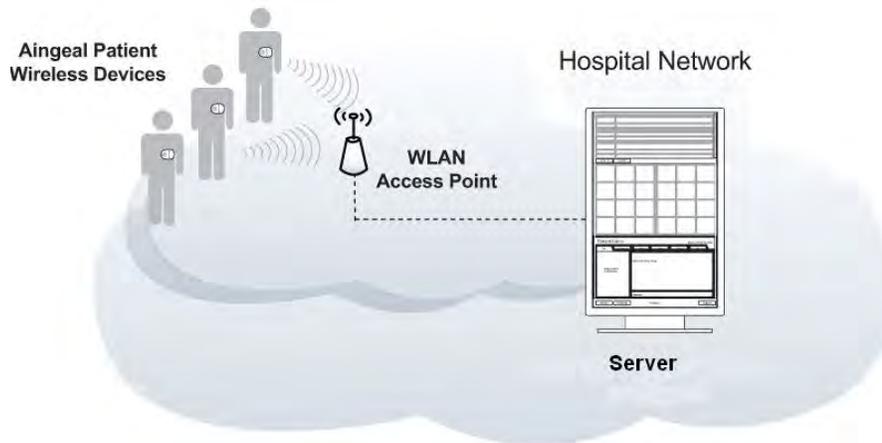
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Aingeal electrode and device applied to patient

System:

The functional diagram of the system is as follows:



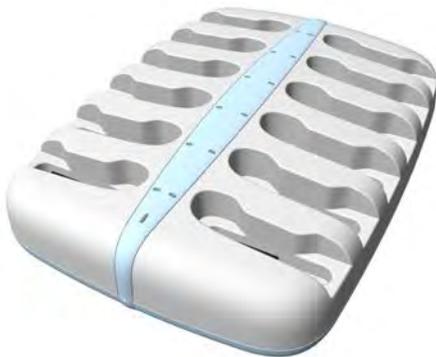
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Aingeal Activity Device



Aingeal Activity Battery



Aingeal Activity Charger



Aingeal Activity Electrode

Indications for Use:

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The device can be used where information on ECG, respiration, heart rate, skin temperature, and activity levels would be useful.

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Patient Population:

Adults

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Healthcare environment

Contraindications:

No contraindications exist

Technology:

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

- AAMI / ANSI ES60601-1:2005 (+C1:09+A2:10) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007 Collateral standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-1-8: 2006 collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-27: 2011 particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 60601-2-49: 2011 Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.
- ISO 80601-2-56: 2009 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- AAMI / ANSI EC12:2000/(R)2010, Disposable ECG electrodes.
- AAMI / ANSI EC57: 2012, Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms

Summary of Performance Data**Bench**

The Aingeal Activity 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.

- Compliance with AAMI ANSI ES60601-1:2005 (+C1:09+A2:10)
- Compliance with IEC 60601-2-49:2011

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- Compliance with ISO 80601-2-56:2009
- Compliance with AAMI EC 57:2012
- Compliance with IEC 60601-1-8:2006
- Compliance with IEC 60601-2-27:2011
- Compliance with IEC 60601-1-2:2007
- Hardware Verification
- System Validation
- Electrode Validation Summary inclusive of AAMI EC12:2000(R)2010 compliance
- Electrode Storage test
- Wireless Coexistence Testing

Testing is documented in **Sections 16 – Software, 17 Electrical Safety and 18 – Performance Testing - Bench** of this submission

Animal

No animal testing was performed

Clinical:

No human clinical testing was performed

Risk Analysis:

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 Aingal Activity System and predicate are both prescription devices.

Design and Technology – The Aingal Activity System and predicate have equivalent design features and technology

Performance and Specifications – The Aingal Activity System has equivalent specifications of performance as the predicate.

Patient Population –

The Aingal Activity System and predicate are indicated for adults

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Environment of Use – Aingeal Activity System and predicate are for healthcare environments

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 Aingeal Activity System is substantially equivalent to the predicate device, and is safe and effective.