510(k) Summary
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April 20, 2011

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Official Contact:

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Proprietary or Trade Name:

Aingeal (VS200)

Common/Usual Name:

Physiological Patient Monitor

Classification Name:

Monitor, physiological, patient (with arrhythmia Detection or alarms)
MHX

Arrhythmia detector and alarm (including ST-segment measurement and alarm)
DSI

Predicate Device:

K071805
Datascope
NetGuard Automated Clinician Alert System

K093976
Proteus Biomedical
Raisin Personal Monitor

K083185
CADI Scientific
CADI SmartSense Wireless Temperature Monitor

K033378
Welch Allyn
Vital Signs Monitor Propaq Lt

Device Description:

The Aingeal (VS200) is a small, lightweight wearable device that is connected to an accessory electrode that is applied to the patient's body. The device wirelessly transmits physiological data relating to ECG, heart rate, respiration, skin temperature and motion to a receiving station via a WiFi connection for display or for analysis by a clinician. The device alerts clinicians when a patient's heart rate changes outside of pre-defined thresholds that can be modified by clinical

staff. There are also on-board algorithms that continuously monitor for, and record ECG on detection of seven cardiac arrhythmias.

Feature / Device	**Aingeal (VS200)**
ECG	1 lead
Arrhythmia Detection	7 arrhythmia detection algorithms
Accelerometer	Yes
Temperature	Yes
Respiration	Yes
Data Transmission	WiFi

Indications for Use:

The Intelesens Vital Signs Monitor Aingeal (VS200) is used to monitor and transmit physiological data to a web based host 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 transmits the data to the host application at user defined intervals or upon the detection of an arrhythmia event.

Patient Population:
Adult

Environment of Use:
Healthcare environment

Contraindications:
None

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Technology:
The Aingeal (VS200) conforms to the following standards:

- IEC 60601-1:2005: Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (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

Materials:
See Section 15 of this submission.

Summary of Performance Data
The Intelesens Aingeal (VS200) was 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.

A risk analysis 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 ISO9001:2008 and ISO13485:2003.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAY 20 2011

Intelesens Ltd.
c/o Mr. Paul Dryden
President, Regulatory Consultant
Promedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K110015
Trade/Device Name: Aingeal VS200
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: May 16, 2011
Received: May 17, 2011

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

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Indications for Use Statement

510(k)-Number: K110015 (To be assigned)

Device Name: Intelesens Vital Signs Monitor Aingeal (VS200)

Indications for Use:

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Prescription Use X **or** **Over-the-counter use**
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110015