Date Prepared December 3, 2013

JAN - 8 2014

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Proprietary or Trade Name: V-Patch System

Common/Usual Name: Physiological Patient Monitor

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

Predicate Device: K100155
Biomedical Systems
TruVue

Device Description:
The V-Patch device is a small, lightweight wearable device that is connected to an accessory electrode that is applied to the patient's body. The electrodes are a proprietary Intelesens design. The patient wearable monitor is named the V-Pod operates on user replaceable coin cells. The device wirelessly transmits physiological data relating to ECG and heart rate to a receiving station - the V-Cell via a wireless ANT connection.

The V-Cell interfaces to the Internet via GPRS allowing for web-based analysis by a clinician on the Canberra System. There are also on-board algorithms that continuously monitor for, and record ECG on detection of nine cardiac arrhythmias and a patient activated event button. The cardiac arrhythmias detected are:

- Bradyarrhythmia
- Ventricular Tachycardia
- Supraventricular Tachycardia
- Ventricular Fibrillation
- Atrial Flutter
- Atrial Fibrillation
- 1st degree Heart Block
- 2nd degree Heart Block
- 3rd degree Heart Block

Nomenclature:
The V-Patch System is composed of the V-Pod, V-Cell and Canberra display as described above.

Indications for Use:
The Intelesens V-Patch System is designed to monitor and transmit ECG 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 or home 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.

The re-usable device is intended to be used with a single use electrode on the patient for up to seven days.

The V-Patch System uses an on-board ECG arrhythmia detection algorithm 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. The V-Patch also has a patient activated button that allows ECG to be recorded and transmitted on-demand should the patient experience any relevant symptoms.

Patient Population:
Adult

Environment of Use:
Healthcare or home environment

Contraindications:
Not to be used on patients where real time monitoring is required
Not to be used on patients with a pacemaker or ICD

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

- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 (VS300)
- 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
- AAMI / ANSI EC38:2007, Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

Summary of Performance Data
The V-Patch 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 IEC 60601-1
- Compliance with IEC 60601-1-2
- System Validation
- Electrode Validation Summary inclusive of AAMI EC12 compliance
- Compliance with AAMI EC 57
- Electrode Storage test
- AAMI ANSI EC38

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 ISO9001:2008 and ISO13485:2003.

Substantial Equivalence

Indications –
The indications for use are equivalent.

Prescriptive – The V-Patch and predicate are both prescription devices.

Design and Technology – The V-Patch and predicate have equivalent design features and technology

Performance and Specifications – The V-Patch has equivalent specifications of performance as the predicate.

Patient Population –
The V-Patch and predicate are indicated for adults

Environment of Use – V-Patch also 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 V-Patch Monitoring System is substantially equivalent to the predicate device, and is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

January 8, 2014

Intelesens Limited
% Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K131000
Trade/Device Name: V-patch system
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor
Regulatory Class: Class II
Product Code: DSI
Dated: December 4, 2013
Received: December 5, 2013

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 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. 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 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,

Owen P. Faris -S

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: _____ (To be assigned)

Device Name: Intelesens V-Patch System

Indications for Use:

The Intelesens V-Patch System is designed to monitor and transmit ECG 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 or home 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.

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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)

Digitally signed by
Owen P. Faris -S
Date: 2014.01.08
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