K103584

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

JUN 10 2011

(a) (1) **Submitted by:**

Envisen Inc.
Block 1, Zone A, Jian Long Industrial Complex
Henggang, Longgang District
Shenzhen 518115
China
Tel +86 755 8882 7227
Fax +86 755 2865 1415

E-mail: feilu@envisen.com

Contact Person: Dr. Fei Lu, Ph.D

Position/Title: General Manager

Date of Preparation: November 1, 2010

Trade Name: Envisen Disposable and Reusable Oximeter Sensors

Common/Classification Name: Oximeter

Product Code: DQA, 21 CFR §870.2700

Class: Class II

(3) **Predicate Device(s):**

510(k)	Device	Manufacturer
K993637	N-395 Pulse Oximeter	Nellcor Puritan Bennett, Inc.
K052186	Nellcor Oximax pulse oximetery sensors	Nellcor Puritan Bennett, Inc.
K093853	Single-patient use disposable sensor series	Nonin Medical, Inc.
K080255	MODEL 7500A Palmsat Pulse Oximeter	Nonin Medical, Inc.
K062605	Philips SpO2 Reusable Sensor, Model M1196A and M1196T	Philips Medical Systems
K083705	BCI WW1020 SPECTRO2 Pulse Oximeter	Smiths Medical PM, Inc. (formerly SIMS BCI)
K910770	CSI 504-US Pulse Oximeter	Criticare Systems, Inc.
K962127	Ohmeda 3800 Pulse Oximeter	GE Healthcare Finland Oy (formerly Ohmeda Medical)
K010463	Datex-Ohmeda Oxygen Saturation Module, M-OSAT and Accessories	GE Healthcare Finland Oy (formerly Datex-Ohmeda, Inc.)

Reason for Submission: New Device(s)

(4) **Description of Device:**

The Envisen Disposable and Reusable SpO2 Sensors are a family of oximeter sensors designed for compatibility with listed predicate oximeter manufacturers/monitors.

Envisen Reusable Oximeter Sensors are finger clip type sensors with specifications validated to meet the requirements for compatibility with each specified manufacturer series. Each finger clip is comprised of a plastic shell with silicone pads which position the optical components to measure through the finger, and a cable with manufacturer specific connector.

Envisen Disposable Oximeter Sensors consist of adhesive medical tape assemblies which are provided in three different configurations for application on adult, pediatric, and infant patients. Each sensor uses a cable with manufacturer specific connector.

All sensors are labeled for compatibility for a specific manufacturer/monitor series and includes the following elements:

- Optical and electronic specifications specific to the monitor type
- Connector configuration specific for the monitor type

Sensor labeling clearly specifies the manufacturer/monitor type with two compatibility statements:

- Compatibility label attached to the sensor cable
- Compatibility information provided on the instructions for use.

Both reusable and disposable sensors utilize configurations (finger clip, adhesive tapes) which have wide industry and clinical acceptance.

(5) **Intended use:**

SpO2 monitoring applications include anesthesia/intra-operative, recovery, ICU/critical care, day surgery, home/chronic care, and transport.

Device Indications for Use:

Envisen Disposable and Reusable Oximeter Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for patients in hospitals, hospital-type facilities, mobile, and home environments.

Prescription Device

(6) **Technological Characteristics:**

The EnviteC Disposable and Reusable SpO2 Sensors utilize the same measurement principles as the listed predicate devices: two wavelengths of light (red, infrared) from light emitting diodes (LED's) illuminate the patient's arterial tissue; and the light transmission through the tissue is measured using a photodiode light detector. The transmission properties vary with the patient's arterial blood saturation and pulse rate.

This method is fundamental to all pulse oximeter sensors and monitors for the non-invasive measurement of functional oxygen saturation (SpO2).

(b) (1) **Non-Clinical Tests Submitted:**

All sensors have been tested to meet current applicable standards for pulse oximeter sensors, including device electrical and thermal safety and EMC (electromagnetic compatibility). All sensors were tested for pulse rate with a listed SpO2 simulator. The devices passed all of the tests.

Patient contact materials meet requirements for biocompatibility.

(2) **Clinical Tests Submitted:**

Clinical testing has been performed under an approved protocol with subject informed consent. Clinical hypoxia test results were obtained in human adult volunteers to validate the accuracy of Envisen Disposable and Reusable Oximeter Sensors versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

(3) **Conclusions from Tests:**

As described in (b)(1) and (b)(2), testing above demonstrates that the Envisen Disposable and Reusable Oximeter Sensors are equivalent to predicate sensors as substantiated by laboratory and clinical testing.

Device safety is supported by compliance testing and by use of biocompatible patient contact materials.

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

JUN 10 2011

Shenzhen Envisen Industry Company Limited
C/O Mr. Stephen H. Gorski
President
Imagenix, Incorporated
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K103584
Trade/Device Name: Envisen Disposable and Reusable Oximeter Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 20, 2011
Received: May 31, 2011

Dear Mr. Gorski:

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 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Envisen Disposable and Reusable Oximeter Sensors

Indications for use:

Envisen Disposable and Reusable Oximeter Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for patients in hospitals, hospital-type facilities, mobile, and home environments.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use _____ (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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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