MAY 0 2 2014
K133064

510(k) Summary in accordance with 21 CFR 807.92

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

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Position/Title: R&D Manager

Date of Preparation: May 2, 2014

(2) **Trade Name:** EnviteC MySign® S Pulse Oximeter, Accessory SpO2 Sensors, and MySign® PC Software

Common/Classification Name: OXIMETER; EAR OXIMETER

Product Code(s): DQA; 21 CFR §870.2700
DPZ; 21 CFR §870.2710

Class: Class II

(3) **Predicate Device(s):** Substantial Equivalence to:

K Number	Model	Manufacturer
K070193	EnviteC OxiPen	EnviteC-Wismar GmbH, a Honeywell Company
K991823	Nellcor N-395	Philips Medical Systems (formerly HP)
K122290	Envitec MySign PC Software (listed accessory of MySign O Oxygen measuring device)	EnviteC-Wismar GmbH, a Honeywell Company

Reason for Submission: New Device(s)

(4) **Description of Device:**

The EnviteC MySign® S Pulse Oximeter is a handheld pulse oximeter monitor validated for use in portable applications, including out of hospital transport.

The MySign® S Pulse Oximeter features large readable numeric displays for SpO_2 and pulse rate and a pulse bar indicator or waveform for visual assessment of pulsation. The device has settable alarms and an audible pulse tone which varies with saturation level.

The MySign® S is offered with a family of Reusable and Disposable SpO_2 Sensors for adult and pediatric applications.

MySign® PC Software may be used to obtain retrospective monitoring data from MySign® series monitors and to perform utility functions such as setting the institution identification.

(5) **Intended use:**

The measurement of functional oxygen saturation of arterial hemoglobin (SpO_2) has been a standard of care in the USA for 20 years. Applications for oximetry include monitoring in the anesthesia, recovery, and critical care environments, as well as transport monitoring and home care.

Indications for Use:

MySign® S is a handheld pulse oximeter with accessory sensors indicated for continuous non-invasive monitoring of the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult and pediatric (excluding neonatal and infant) patients in hospitals, hospital-type facilities, and mobile transport units. For professional use only.

(6) **Technological Characteristics:**

The EnviteC MySign® S Pulse Oximeter and Accessory SpO_2 Sensors employ the same technological characteristics as the listed predicate devices to determine arterial functional oxygen saturation: arterially perfused tissue is illuminated sequentially by two wavelengths of light emitted by light emitting diodes (LED's), and the time varying absorbance of the tissue is measured from a photodiode light sensor. This method is characteristic of all pulse oximeter monitors and sensors which are the subject of this submission as well as the predicate devices.

Comparison of Technological Features to Predicate Device(s):

Product/Feature	EnviteC MySign® S Pulse Oximeter Monitor	EnviteC OxiPen Pulse Oximeter	Nellcor N395 Pulse Oximeter
Manufacturer	EnviteC-Wismar GmbH by Honeywell	EnviteC-Wismar GmbH by Honeywell	Nellcor, Inc (now Covidien)
510(k) Number	(pending this submission)	**K070193**	**K991823**
Patient Population	Adult through pediatric (not infant or neonatal) patients	Adult through pediatric (not infant or neonatal) patients	Adult through neonatal patients
Indications:	MySign® S is a handheld pulse oximeter with accessory sensors indicated for continuous non-invasive monitoring of the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult and pediatric (excluding neonatal and infant) patients in hospitals, hospital-type facilities, mobile units, and home environments.	The EnviteC OxiPen Pulse Oximeter is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO_2), and pulse rate (measured by SpO_2 sensor accessories). The monitor is intended for use on adult and pediatric patients in hospitals, hospital-type facilities, mobile, and home environments.	The intended use of the N-395 Pulse Oximeter is the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. For use with neonatal, pediatric and adult patients, in hospitals, hospital-type facilities and intra-hospital transport environments. For prescription use only.
Use	Continuous monitoring of functional oxygen saturation with alarms	Spot monitoring of functional oxygen saturation (no alarms)	Continuous monitoring of functional oxygen saturation with alarms
Measurement principle	Two wavelength pulse measurement to obtain functional oxygen saturation	Two wavelength pulse measurement to obtain functional oxygen saturation	Two wavelength pulse measurement to obtain functional oxygen saturation
SpO_2 range	1-100%	0-100%	1-100%
SpO_2 accuracy	Monitor: 70-100%: A_{RMS} = ± 2 % (with SoftTip R3211-12 MySign) Accuracy claim varies slightly by sensor type	Monitor: 70-100%: A_{RMS} = 2.0 Accuracy claim varies slightly by sensor type	Monitor: 70-100%: ± 2 digits Neonatal: ± 3 digits Saturation (%SpO2 ±1 SD)
Pulse rate range	0-300 BPM	20-300 BPM	20-250 BPM
Pulse rate accuracy	± 3 BPM (30-250 BPM)	± 3 BPM (20-300 BPM)	± 3 digits (20-250)

Product/Feature	EnviteC MySign® S Pulse Oximeter Monitor	EnviteC OxiPen Pulse Oximeter	Nellcor N395 Pulse Oximeter
Available Oximetry Sensors supported by IFU's	Finger Clip; SoftTip Finger Sensor(s); SoftTip+; Ear Clip; Disposable Adult/Pediatric	Finger Clip; SoftTip Finger Sensor	Full range of Nellcor reusable/disposable sensors including, Finger Clip, Ear Clip, Y Sensor, Disposable Adult-Neonatal
Visible & Auditory Alarms	Audible Alarms/Alerts 55-75 db(A)	Audible alerts for sensor off, disconnect, power off	Audible Alarms/Alerts, outputs vary by priority (high, medium, low)
IFU structure	Comprehensive user manual, separate accessory instructions	Comprehensive user manual, separate accessory instructions	Comprehensive user manual, separate accessory instructions

Product/Feature	EnviteC MySign® PC Software (new version to support MySign S)	EnviteC MySign® PC Software (cleared version for MySign O)
Manufacturer	EnviteC-Wismar GmbH by Honeywell	EnviteC-Wismar GmbH by Honeywell
510(k) Number	(*pending - this submission*)	**K122290**
Devices Supported	MySign S (new) MySign O (existing)	MySign O
PC Operating System	Microsoft Windows XP or later, Microsoft .NET 4.0 Framework	Microsoft Windows XP or later, Microsoft .NET 3.5 or 4.0 Framework
Device connection	USB Serial Port	USB Serial Port
Basic menu functions	Dataset, PC Data, Patient Data, Export to Excel, Save, Print (to PDF), Delete, System Settings	Dataset, PC Data, Patient Data, Export to Excel, Save, Print (to PDF), Delete, System Settings
Parameters Displayed	%SpO2, Pulse Rate, % O2, alarm limits at time of measurement (tabular or graphical view)	% O2, alarm limits at time of measurement (tabular or graphical view)
Data present-ation options	Tabular (data listing) Trend Chart	Tabular (data listing) Trend Chart

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

The EnviteC MySign® S Pulse Oximeter and Accessories were tested in accordance with current applicable standards for medical device electrical safety and electromagnetic compatibility and particular standards for pulse oximeter monitors, including the following recognized standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1, General Requirements for Safety
- IEC 60601-1-2, Medical Electrical Equipment - Collateral Standard. Electromagnetic Compatibility Requirements & Tests
- ISO 80601-2-61, Medical Electrical Equipment - Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeters.
- IEC 60601-1- 8, Medical Electrical Equipment - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Risk management and software validation was performed on the device, Including MySign® PC Software, in accordance with established development processes per the following:

- ANSI/AAMI/ISO 14971, Medical devices-Risk management-Application of risk management to medical devices
- IEC 62304, Medical Device Software, Software Life Cycle Processes
- FDA/ODE Guidance for the Content

Sensor patient contact materials meet applicable standards for biocompatibility.

(2) **Clinical Tests Submitted:**

Clinical testing was performed to validate the performance and accuracy of the MySign® S Pulse Oximeter with SpO_2 Sensors under controlled hypoxia versus arterial oxygen saturation as determined by co-oximetry. All testing was performed under an institutionally approved protocol with subject informed consent. Clinical test results support the stated accuracy claims for the specified range of 70% to 100% SaO_2.

(3) **Conclusions from Tests:**

As described in (b)(1) and (b)(2) above, EnviteC MySign® S Pulse Oximeter and Accessories are equivalent to predicate devices as substantiated by parameter, bench, and clinical testing. Device safety is substantiated by testing to applicable standards and by biocompatibility of patient contact materials.

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

May 2, 2014

EnviteC-Wismar GmbH
c/o Mr. Stephen Gorski
Imagenix Incorporated
S65 W35739 Piper Road
Eagle, WI 53119

Re: K133064
Trade/Device Name: EnviteC MySign® S Pulse Oximeter, Accessory SpO2 Sensors, and MySign® PC Software
Regulation Number: 21 CFR 870.2700
Regulation Name: OXIMETER
Regulatory Class: Class II
Product Code: DQA, DPZ
Dated: March 28, 2014
Received: April 2, 2014

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 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" (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,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K133064**

Device Name: MySign® S Pulse Oximeter and Accessories

Indications for use:

MySign® S is a handheld pulse oximeter with accessory sensors indicated for continuous non-invasive monitoring of the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult and pediatric (excluding neonatal and infant) patients in hospitals, hospital-type facilities, and mobile transport units. For professional use only.

Prescription Use ____X____ AND / 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)

Neel J. Patel -S
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