K122290

JAN 23 2013

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

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

EnviteC-Wismar GmbH by Honeywell
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Contact Person: Marko Sproessel

Position/Title: Research and Development Manager

Date of Preparation: January 3, 2013

(2) **Trade Name:** EnviteC MySign® O Oxygen Measuring Device

Common/Classification Name: Analyzer, Gas, Oxygen, Gaseous-Phase

Product Code(s): 21 CFR §868.1720; CCL

Class: Class II

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

K Number	Model	Manufacturer
K040484	Max O2 Plus – Model OM25 ME	Maxtec, Inc.
K063488	Max O2 CU	Maxtec, Inc.
K082655	EnviteC Medical Oxygen Sensors (including sensor OOM111)	EnviteC-Wismar GmbH

Reason for Submission: New Device

(4) **Description of Device:**

The EnviteC MySign® O Oxygen Measuring Device is a hand held oxygen monitor which uses the established technology of the EnviteC electro-galvanic oxygen sensor type OOM111. The EnviteC OOM111 medical oxygen sensor has been previously evaluated and cleared under 510(k) **K082655**.

The MySign® O Oxygen Measuring Device incorporates a medical oxygen sensor placed in the inspired air path or gas supply, a sensor cable, and a

monitor to display the measurements. The device is intended for continuous or spot monitoring of inspired oxygen concentrations in breathing gas and provides settable low and high alarm limits.

The optional MySign® PC Software can be used to configure MySign® devices and to transmit data from the device to the PC for the readout of measurement data which is stored in the memory of MySign® monitor. The PC software is not intended for diagnostic functions nor will it influence essential performance functions of the monitor – the MySign® O monitor will not perform measurements when PC connected.

(5) **Intended use:**

Inspired oxygen monitors have widespread use for continuous or spot monitoring of inspired oxygen concentrations in breathing gas and air supplies.

Indications for Use:

The oxygen measuring device MySign® O is designed for continuous or spot monitoring of inspired oxygen concentrations in breathing gas.

MySign® O can be used for monitoring the breathing gases dispensed by the following devices:

Anaesthesia breathing systems
Respiratory equipment
Infant incubators
Oxygen therapy systems

The system is suitable for use inside hospitals as well as during transport (except by air), emergencies, and artificial respiration provided at home.

Prescription device

(6) **Technological Characteristics:**

The EnviteC MySign® O Oxygen Measuring Device utilizes the same measurement principles as the predicate devices to measure oxygen: an electro-galvanic oxygen sensor produces an electrical voltage in relation to the amount of oxygen present. The monitor utilizes a microprocessor with analog to digital converter to obtain the sensor voltage and displays the calculated oxygen percentage. This method is characteristic of the oxygen sensor and monitor which are the subject of this submission as well as of the predicate device characteristics.

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

The EnviteC MySign® O Oxygen Measuring Device was tested in accordance with current applicable standards for medical device electrical safety and electromagnetic compatibility and particular standards for respiratory gas 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 21647, Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors.
- 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 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 of Premarket Submissions for Software Contained in Medical Devices

Accessories for placement of the oxygen sensor in the path of the inspired air or gas supply were tested to meet applicable standards for biocompatibility per EN ISO 10993, Biological evaluation of medical devices.

Device parameters were compared to the listed predicate devices, and tested for linearity, measurement accuracy, and drift. The EnviteC MySign® O Oxygen Measuring Device met test acceptance criteria established by the respiratory gas monitoring standard.

(2) **Clinical Tests Submitted:**

(None)

(3) **Conclusions from Tests:**

As described in (b)(1) and (b)(2) above, the EnviteC MySign® O Oxygen Measuring Device is equivalent to the listed predicate devices as substantiated by parameter and bench testing and evaluation. Device safety is substantiated by risk management activities, and internal and independent laboratory testing to applicable standards.

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

January 23, 2013

EnviteC-Wismar GmbH
C/O Mr. Stephen H. Gorski
Imagenix, Incorporated
S65 W35739 Piper Road
EAGLE WI 53119

Re: K122290
Trade/Device Name: MySign® O Oxygen Measuring Device
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: II
Product Code: CCL
Dated: December 20, 2012
Received: December 26, 2012

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,

Kwame O. Ulmer

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

Enclosure

Exhibit C

Indications for Use

510(k) Number (if known): K122290

Device Name: MySign® O Oxygen Measuring Device

Indications For Use:

The oxygen measuring device MySign® O is designed for continuous or spot monitoring of inspired oxygen concentrations in breathing gas.

MySign® O can be used for monitoring the breathing gases dispensed by the following devices:

Anaesthesia breathing systems

Respiratory equipment

Infant incubators

Oxygen therapy systems

The system is suitable for use inside hospitals as well as during transport (except by air), emergencies, and artificial respiration provided at home.

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)

Albert E. Moyal

Albert E. Moyal
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for LS

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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