K082655

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

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

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NOV 2 5 2008

Contact Person: Mr. Marcus Lindenlaub

Position/Title: Managing Director

Date of Preparation: September 8, 2008

(2) **Trade Name:** EnviteC Medical Oxygen Sensors

Common/Classification Name: Oxygen Gas Analyzer

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

Class: Class II

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

K Number	Model	Manufacturer
K972992	Ceramatec MAXCELL and CAG Galvanic Oxygen Sensors	Ceramatek (Maxtec, Inc.)

Reason for Submission: New device

(4) **Description of Device:**

The subject of this 510(k) is a family of EnviteC Medical Oxygen Sensors which may be used as industry replacement types with various medical inspired-oxygen measuring devices.

The EnviteC Medical Oxygen Sensors all utilize the commonly accepted electro-galvanic operating principle with defined variations in the mounting configuration and electrical connections to correspond to common industry family replacement types.

(5) **Intended use:**

Medical oxygen sensors have widespread use to sense the quantity of inspired oxygen gas delivered to a patient. Applications include anesthesia monitoring equipment, critical care monitors, and respiratory care including oxygen concentrators.

Indications for Use:

The EnviteC Medical Oxygen Sensors are intended to replace the original oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

(6) **Technological Characteristics:**

The EnviteC Medical Oxygen Sensors employ the same technological characteristics as the predicate device – the electro-galvanic measurement principle.

The sensors utilize two electrodes, a precious metal cathode and a lead anode immersed in a liquid electrolyte solution, to produce an electrical voltage in relation to the amount of oxygen present. Specific sensors include internal temperature-compensation components to adjust the output voltage in relation to temperature.

The sensors are housed in a plastic can-shaped configuration which can be screwed or mounted to the inspired air or gas supply. Across the family of sensors offered, variations in the mounting configuration and electrical connections correspond to common industry replacement types.

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

The sensors were evaluated in accordance with the applicable elements of standards for respiratory gas monitors. Compliance tests included evaluation of basic safety, mechanical characteristics, and environmental operation and storage conditions. The devices passed all of the compliance tests.

The sensors were evaluated for device performance characteristics including signal characteristics in the presence of temperature, pressure, humidity, and interfering gases. The devices met all of the performance criteria.

(2) **Clinical Tests Submitted:**

(none / none required)

(3) **Conclusions from Tests:**

As described above, the EnviteC Medical Oxygen Sensors meet the applicable requirements for respiratory gas sensors as substantiated by parameter and compliance testing. Equivalence to the predicate device(s) is substantiated by detailed comparison of specifications and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EnviteC-Wismar GmbH
C/O Mr. Stephen Gorski
Imagenix, Incorporated
S65 W35739 Piper Road
Eagle, Wisconsin 53119

NOV 2 5 2008

Re: K082655
Trade/Device Name: EnviteC Medical Oxygen Sensors Types OOM101; OOM102 /-1; OOM103 /-1/-1M; OOM104;OOM105;OOM106;OOM107 /-2; OOM110;OOM111;OOM201;OOM202 /-1/-2/-2S;OOM204
Regulation Number: 21 CFR 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: II
Product Code: CCL
Dated: August 14, 2008
Received: September 12, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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: EnviteC Medical Oxygen Sensors types OOM101; OOM102 /-1; OOM103 /-1 /-1M; OOM104; OOM105; OOM106; OOM107 /-2; OOM110; OOM111; OOM201; OOM202 /-1 /-2 /-2S; OOM204

Indications for use:

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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)

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

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