FEB 1 1 2005

K043463

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

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

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Contact Person: Bernd Lindner

Position/Title: Managing Director

Date of Preparation: November 1, 2004

(2) **Trade Name:** EnviteC Reusable Multi-site Y SpO_2 Sensors

Common/Classification Name: OXIMETER

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

Class: Class II

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

K Number	Model	Manufacturer
K944760	Nellcor Dura-Y Oxygen Transducer, Ear Clip	Nellcor Puritan Bennett, Inc.
K962127	Ohmeda 3800 Pulse Oximeter	Datex-Ohmeda, Inc.
K893877	Biochem 3100 Oximeter	BCI-Biochem International, Inc.
K910770	CSI 504-US Pulse Oximeter	CSI-Criticare Systems, Inc.
K010463	Datex-Ohmeda S/5 Oxygen Saturation Module, M-OSAT and Accessories	Datex-Ohmeda, Inc.
K032979	Philips Reusable SpO2 Sensors	Philips Medizin Ayateme Böeblingen GmbH (*formerly HP*)
K890033	Model 8700 Pulse Oximeter	Nonin Medical, Inc.
K993979	Model 2001MARSpO2 Pulse Oximeter	Novametrix Medical Systems, Inc.

Reason for Submission: New Device(s)

(4) **Description of Device:**

The EnviteC Reusable Multi-site Y SpO_2 Sensors are a family of oximeter sensors designed and validated for compatibility with the predicate oximeter manufacturers listed above.

EnviteC's Reusable Multi-site Y SpO_2 Sensors consist of a connector and a cable which divides at the distal end into two sensor housings. One housing contains a dual LED light source, and the other contains a light sensitive photodetector. The housings may be positioned on various body locations, including finger, thumb, toe, or foot, and are affixed by a medical grade tape.

A unique Y sensor exists for each manufacturer above, and each Y sensor has unique labeling and specifications designed for compatibility with the specific monitor manufacturer (Nellcor, CSI, etc.).

Each sensor type includes the following unique features:
- Connector pin-outs specific for the manufacturer type
- Component specifications specific for the manufacture type

Each sensor also specifies the manufacturer type with two compatibility statements:
- One printed on or attached to the sensor
- One on the instructions for use.

(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:

EnviteC Reusable Multi-site Y SpO_2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Not recommended for use on the ear.

Prescription device.

(6) **Technological Characteristics:**

The EnviteC Reusable Multi-site Y SpO_2 Sensors employ the same technological characteristics as the predicate devices to determine arterial 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 Y sensors which are the subject of this submission as well as the predicate devices.

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

The sensors were tested in accordance with applicable standards for medical device Electrical Safety and Electromagnetic Compatibility. The sensors (with predicate device monitors) were tested for pulse rate with a listed simulator. Sensor electro-optical parameters were measured and compared to predicate devices. The Y sensors passed all of the tests.

Sensor patient contact materials (housing and attachment tape) meet applicable standards for biocompatibility.

(2) **Clinical Tests Submitted:**

Clinical testing was performed to validate the performance and accuracy of the EnviteC Reusable Multi-site Y 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 Reusable Multi-site Y SpO_2 Sensors are equivalent to predicate sensors 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
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Envitec-Wismar GMBH
Mr. Stephen Gorski
Imagenix, Incorporated
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K043463
Trade/Device Name: EnviteC Reusable Multi-Site Y SpO_2 Sensors
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 12, 2004
Received: December 15, 2004

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.

Indications for Use

510(k) Number (if known):

Device Name: EnviteC Reusable Multi-site Y SpO_2 Sensors

Indications for use:

EnviteC Reusable Multi-site Y SpO_2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Not recommended for use on the ear.

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

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
(510(k) Number) K043463