K060675

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

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

EnviteC-Wismar GmbH
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JUL 17 2006

Contact Person: Bernd Lindner

Position/Title: Managing Director

Date of Preparation: December 2, 2005

(2) **Trade Name:** Reusable EnviteC SoftTipY® SpO2 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
K043463	Reusable Multi-site Y SpO2 Sensors	EnviteC-Wismar GmbH

Reason for Submission: Device Modification to Y-Sensors

(4) **Description of Device:**

EnviteC's Reusable SoftTip Y sensors are a modification of EnviteC's Multi-Site Y SpO_2 Sensors listed in K043463. The modification integrates the two Y-sensor housing tips into a single molded rubber tube which facilitates placement on a digit. This modification preserves in its entirety the original optical geometry and specifications of the predicate Y-sensors.

Like the Multi-site Y SpO_2 sensors, EnviteC's SoftTip Y SpO_2 sensors consist of a connector and a duplex cable which divides at the distal end to the LED light source and light sensitive photodetector.

The EnviteC SoftTip Y SpO_2 Sensors comprise a family of oximeter sensors designed and validated for compatibility with the same oximeter monitor manufacturers as the Y-Sensors.

A unique SoftTip Y sensor exists for each manufacturer series, and each SoftTip 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 SoftTip 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, and infant patients in hospitals, hospital-type facilities, mobile, and home environments.

Prescription device.

(6) **Technological Characteristics:**

The EnviteC SoftTip 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. The optical geometry and electro-optical specifications of the unmodified Y-sensors are preserved in the SoftTip Y modifications.

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

Consistent with internal design control processes, a detailed risk analysis was performed to determine the impact of the housing change, and a

compilation of tests performed has been provided. The modified sensors were tested in accordance with applicable standards for medical device Electrical Safety, temperature, and Electromagnetic Compatibility. The SoftTip Y SpO_2 sensors passed all of the tests.

(2) **Clinical Tests Submitted:**

As determined by the risk analysis and specification comparison, the clinical hypoxia testing for the predicate Y SpO_2 Sensors is valid for the SoftTip Y SpO_2 sensors because of the narrow scope of the modifications. 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 SoftTip Y SpO_2 Sensors are equivalent to the unmodified Y SpO_2 Sensors as substantiated by parameter and bench testing determined by risk analysis of the modifications. Device safety is further substantiated by testing to applicable compliance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2006

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

Re: K060675
Trade/Device Name: EnviteC Reusable SoftTip Y SpO_2 Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 6, 2006
Received: July 7, 2006

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.

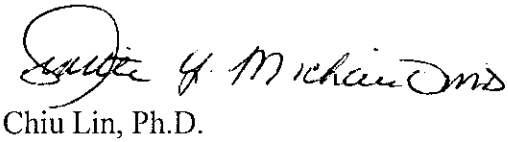
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 Reusable SoftTip Y SpO_2 Sensors

Indications for use:

EnviteC Reusable SoftY 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, and infant patients in hospitals, hospital-type facilities, mobile, and home environments.

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)

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...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
..., Number: K060675