K102270

FEB 22 2011

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

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

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Contact Person: Marcus Lindenlaub

Position/Title: Managing Director

Date of Preparation: December 28, 2010

(2) **Trade Name:** EnviteC Reusable SpO_2 Sensors type Nihon Kohden

Common/Classification Name: OXIMETER; EAR OXIMETER

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

Class: Class II

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

K Number	Model	Manufacturer
K011918	BSM-2300 Series Bedside Monitor and Accessories (pulse oximeter sensor accessories considered)	Nihon Kohden America, Inc.

Reason for Submission: New Device(s)

(4) **Description of Device:**

The EnviteC Reusable SpO_2 Sensors type Nihon Kohden are pulse oximeter sensors designed and validated for compatibility with the predicate oximeter manufacturer.

EnviteC's Reusable SpO_2 Sensors type Nihon Kohden are comprised of a connector and a cable which terminates into a sensor housing. One housing half contains a dual LED light source, and the other half contains a light sensitive photodetector for pulse oximetry by transmittance method. Two types of sensor housings are offered in this submission:

- A soft rubber finger sensor with unitary sealed tube type construction (two sizes: large and medium)
- An ear clip with rigid halves positioned by mild spring force and an ear hanger for the cable

Each sensor has unique labeling and specifications designed for compatibility with the specific monitor manufacturer.

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

Each sensor clearly 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 SpO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult and pediatric (excluding neonatal and infant) patients in hospitals, hospital-type facilities, mobile units and home environments.

Prescription device.

(6) **Technological Characteristics:**

The EnviteC Reusable SpO_2 Sensors type Nihon Kohden 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 pulse oximeter 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 current applicable standards for medical device electrical safety and electromagnetic compatibility and particular standards for pulse oximetry. The sensors (with predicate device monitors) were tested for pulse rate with a listed simulator. Sensor electro-optical parameters were compared to predicate devices. All sensors met the acceptance criteria.

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 EnviteC Reusable SpO_2 Sensors type Nihon Kohden 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 SpO_2 Sensors type Nihon Kohden are equivalent to predicate sensors as substantiated by parameter, bench, and clinical testing. Device safety is substantiated by risk management/risk analysis activities, internal and third party laboratory 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 Room –WO66-G609
Silver Spring, MD 20993-0002

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

FEB 22 2011

Re: K102270
Trade/Device Name: EnviteC Reusable SpO2 Sensors type Nihon-Kohden
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: January 25, 2011
Received: January 26, 2011

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,

for

Anthony D. Watson, B.S.,M.S., M.B.A.
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 SpO_2 Sensors type Nihon-Kohden

Indications for use:

EnviteC Reusable SpO_2 Sensors are indicated for continuous non-invasive monitoring of 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.

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

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use _____ (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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