K082546
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Unmedical Medical Supplies Inc
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510(k) Section 5

510(K) Summary

DEC 0 2 2008

Submitter Information:
Unimed Medical supplies Inc
No.37, yanshan Road, Shekou, Shenzhen, China 518067

Contact:
Mr. Don Melnikoff
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Date Prepared: 8/20/08

Trade Name: Unimed compatible oximeter sensors
Common Name: SPO2 Sensor (accessories to pulse Oximeter)
Product Classification: Oximeter (DQA), per 21 CFR 870.2700

Applicable Part Numbers:

U410-09	Datex Compatible Adult Finger Clip Reusable Sensor
U410-02	Ohmeda Compatible Adult Finger Clip Reusable Sensor
U403S-91	Phillips Compatible Adult Soft Tip Reusable Sensor

Predicate Information:

Unimed Sensors	**Predicate 510(K)**	**Predicate Manufacturer/Models**
U4XX Series	K053420	Tenacore Holdings, Inc. Adult Finger Clip Probe
U4XXS Series	K053420	Tenacore Holdings, Inc. Adult Soft ~~Cuff~~ Tip Probe

Description:

Unimed's Spo2 reusable sensors are designed to function the same as the compatible Original Equipment Manufacturer (OEM) Pulse Oximeter Sensor. The sensors contain two specific wavelength LEDs and a photo detector assembled into the silicon pads. The sensor cable terminates into an OEM compatible connector. The sensors use optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter.

Intended Use:
The SpO2 finger sensors are indicated for use to measure the approximate, non-invasive and continuous arterial oxygen saturation and pulse rate of patients weighting more than 40kg.

Manufacturing Facility:
Unimed Medical Supplies inc is the China based manufacturer and distributor of medical cables and accessories. 2500 square meters facility is equipped with all tools and equipments required to produce high quality cables and lead wires.
Unimed is a CE certificated of Class II products and ISO13485-2003 full quality management registered company.

Technology Comparison:
The Unimed sensors employ the same technological characteristics as the predicate devices to determine arterial oxygen saturation: Arterially perfused tissue is illuminated sequentially by two different wavelengths of LEDs, and the time varying absorbance of tissue is measured by a photo detector.
The method is characteristic of all sensors that are subject of this submission as well as the predicate devices.

Performance date & Conclusions:

Performance testing was conducted during clinical hypoxia studies conducted in an independent lab and was shown to validate performance claims and accuracy. Bench testing was performed to verify pulse rate accuracy. Biocompatibility was confirmed for all patient contact materials per ISO 10993.

Electrical safety and electromagnetic testing was also performed per IEC 60601-1

All testing was performed in accordance with ISO 9919 and supported the conclusion that the devices were safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Unimed Medical Supplies Incorporated
C/O Mr. Don Melnikoff
Biomedical Engineering Consultant
Don Melnikoff
W322S8863 McCarthy Drive
Mukwonago, Wisconsin 53149

DEC 0 2 2008

Re: K082546
Trade/Device Name: Unimed Oximetry Finger Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 25, 2008
Received: September 3, 2008

Dear Mr. Melnikoff:

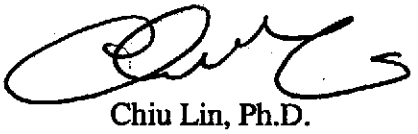
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 276-0120. 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): N/A

Device Name: Unimed oximetry finger sensors

Indications For Use:

The SpO2 finger sensors are indicated for use to measure the approximate, non-invasive and continuous arterial oxygen saturation and pulse rate of patients weighting more than 40kg.

Prescription Use _X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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: K 082566

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