K032831

AUG 3 1 2004

510(k) Summary of Safety and Effectiveness

PRO_2® Pulse Reflectance Oximeter System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Contact Person

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ConMed Corporation
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Date Prepared:

September 10, 2003

Name of Device

Pro_2® Pulse Reflectance Oximeter System

Classification Names

Oximeter

Device Classification

Regulatory Class:	Class II
Product Code:	74 DQA
Classification Panel:	Cardiovascular Device Panel
Regulation Number:	21 CFR 870.2700

Predicate Devices

K012706	IM2001 Pulse Oximeter	Imagyn Medical Technologies
K012891	OxiMAX Pulse Oximetry System with N-595 Pulse Oximeter	Nellcor Puritan Bennett, Inc.

Description of Device

The Pro_2® Pulse Reflectance Oximeter System consists of a reusable sensor that emits and detect red and infrared light, a flexible disposable sensor holder to attach the sensor to the skin, a connecting cable, and a monitor incorporating control, processing, and display units.

The Pro_2® Monitor contains an internal battery to power the unit when AC power is not available. The monitor displays the percentage of oxygen saturation in the blood, pulse rate, signal quality, and alarms.

The Pro_2® Sensor geometry includes light sources that emit light in three different wavelengths, and detection areas defined by two photodetector rings arranged concentrically with the light sources in the center. The rings constitute an annular shape, which allow a multi-path acquisition of signals from a larger tissue area. The measurement of SpO_2 is dependent upon specific wavelengths of light detected by its sensor.

The Pro_2® device has a disposable sensor holder; Model # AHL-200 for adults and pediatric use. The Pro_2® Sensor Holder provides optical isolation for external light and is attached to the skin via adhesive that is incorporated as part of the Sensor Holder.

Indications For Use

The Pro_2® Pulse Reflectance Oximeter System is indicated for the continuous, non-invasive monitoring Pro_2® Pulse Reflectance Oximeter System of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The Pro_2® is intended to monitor arterial saturation on the back and forehead locations in pediatric and adult populations. The Pro_2® is for use in hospital, hospital-type facilities, and intra hospital transport environment.

Nonclinical Performance

The Pro_2® Pulse Reflectance Oximeter System was tested and passed all required electrical and biocompatibility testing.

Clinical Performance

The Pro_2® Pulse Reflectance Oximeter System performance was tested with clinical data and the results met the acceptable criteria.

Conclusion

The Pro_2® Pulse Reflectance Oximeter System is substantially equivalent to the following 510(k) cleared devices:

Imagyn IM2001 Pulse Reflectance Oximeter (K012706)

Nellcor OxiMAX Pulse Oximetry System with N-595 Pulse Oximeter (K012891)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2004

Imagyn Medical Technologies, Incorporated
C/O Ms. Ira Duesler
Director, Regulatory Affairs/Quality Assurance
ConMed Corporation
525 French Road
Utica, New York 13502

Re: K032831
Trade/Device Name: PRO_2 Plus Reflectance Oximeter System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 27, 2004
Received: July 29, 2004

Dear Ms. Duesler:

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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for 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: K032831

Device Name: PRO_2 Pulse Reflectance Oximeter System

Indications for Use: The PRO_2 Pulse Reflectance Oximeter System is indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR). The PRO_2 is intended to monitor arterial saturation on the back or forehead locations in pediatric and adult populations. The PRO_2 is for use in hospitals, hospital-type facilities and intra-hospital transport environment.

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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