K083448

510(k) Summary of Safety and Effectiveness

Applicant:	ConMed Corporation
Address:	525 French Road Utica, NY 13502
Telephone Number:	(315) 624-3219
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Contact Person:	Sarah Rizk Regulatory Affairs Specialist
Date Prepared:	August 18, 2009
Proprietary Name:	Unimed 2400GN Adapter Cable
Common/Classification Name:	Pulse Oximeter cable
Product Code:	DQA
Regulation Number:	870.2700 (Class II)
Predicate Devices:	Masimo AC-1 Adapter Cable K033349

AUG 20 2009

Device Description

The Unimed 2400GN cable is intended to be used with an SpO_2 monitoring device. The cable connects SpO_2 sensors placed at appropriate sites on the patient to the monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional. It allows digital information exchange between the sensor and monitor to accurately read the arterial oxygen saturation (SpO_2) and pulse rate of the patient.

Indications for Use

The Unimed model 2400GN adapter cable is intended to be used as an accessory to connect the Nellcor Oximax 595 pulse oximeter monitor to Dolphin pulse oximetry sensors for the continuous noninvasive monitoring of peripheral functional oxygen saturation (SpO2) and pulse rate (PR) in adult, pediatric, and infant patients in hospitals and hospital-type environments.

Non-Clinical Testing

The ConMed 2400GN cable underwent performance testing in accordance with ConMed's Hypoxia Study Report #SPR-08-128. The ConMed (UniMed) 2400GN adapter cable and Dolphin SpO2 sensor combination was compared to Nellcor SpO2 sensors when both were used on a Nellcor N-595 pulse oximeter (over the range of 70% - 100%).

Volunteers were enrolled in the study. Readings for SpO2 and heart rate were taken every 30 seconds over a 7 minute test duration on volunteers who were subjected to a progressive induced hypoxia. Test results verified relative equivalence between the ConMed (UniMed) 2400GN adapter cable and Dolphin SpO2 sensor to the Nellcor SpO2 sensors for both SpO2 and heart rate.

Clinical Testing

A clinical evaluation was conducted on 27 May 09 at the University of California at San Francisco to compare SpO_2 readings using ConMed Dolphin SpO_2 sensors coupled to Nellcor OxiMax 595 pulse oximeter via a UniMed 2400GN adapter cable with SaO_2 readings obtained via a CO-oximeter. A total of 10 subjects were consented and examined. All effort was made to randomly select subjects across a broad array of demographics, including age, gender, and skin color. The purpose of this study was to evaluate the accuracy of the Dolphin/UniMed device combination when used with a Nellcor OxiMax 595 pulse oximeter.

Conclusion

Supporting information per this premarket submission confirms that the Unimed 2400GN Adapter Cable is substantially equivalent to its predicate device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Sarah Rizk
Regulatory Affairs Specialist
ConMed Corporation
525 French Road
Utica, New York 13502

AUG 20 2009

Re: K083448
Trade/Device Name: Unimed Model 2400GN Adapter Cable
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 7, 2009
Received: August 10, 2009

Dear Ms. Rizk:

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.

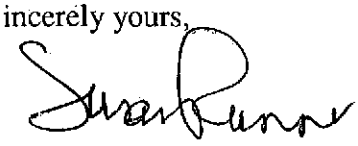
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting Division 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): K083448

Device Name: Unimed Model 2400GN Adapter Cable

Indications for Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083448