DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 6, 2015

Unimed Medical Supplies, Inc.
Xinmei Tan
QA and RA Manager
No. 37, Yanshan Road, Shekou
Shenzhen, 518067
CHINA

Re: K142832
Trade/Device Name: Unimed Disposable and Reusable SpO2 Sensors
Models: U103-01, U103S-01, U403-01, U403-06, U403-07, U403-08, U403-125, U403S-01, U410-03, U503-01, U543-01, N543-01
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 29, 2014
Received: January 6, 2015

Dear Ms. Tan,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith
Director
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Office of Device Evaluation
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142832

Device Name
Unimed Disposable And Reusable Spo2 Sensors

Indications for Use *(Describe)*
Unimed Disposable and Reusable SPO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40kg, pediatric patients weighing 10 -50 kg, and neonatal patients weighing no less than 3 Kg.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 510(K) Summary

1. Prepared Date: 2014-12-25

2. Submitter Information

Name	Unimed Medical Supplies Inc
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Tel	+86-755 26695165
Fax	+86-755 26697984
Establishment Registration No.	3007307487

3. Contact Person

Contact person	Tan xinmei
Title	QA&RA manager
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Tel	+86-755 26695165
Fax	+86-755 26697984
E-mail	tanxinmei@unimed.cn

4. Manufacturer Information

Name	Unimed Medical Supplies Inc
Address	No. 37, Yanshan Road, Shekou, Shenzhen, China 518067
Establishment Registration No.	3007307487

5. Proposed Device Information

Trade Name	Unimed Disposable and Reusable SPO2 Sensors
Common name	Oximeter
Regulatory class	II
Production regulation	21 CFR §870.2700
Product code	DQA
Panel	Cardiovascular

6. Predicate Device Information

510(K)No.	Trade Name/model	Submitter
K100077	Solaris Medical Technology, Inc. Reusable & Disposable SPO2 Sensors	Solaris Medical Technology, Inc.
K111888	Masimo LNOP/M-LNCS/LNCS	Masimo Corporation

	Multisite-L Oximetry Sensors	
K082546	Unimed compatible oximeter sensors	Unimed Medical supplies Inc

7. Device description

The Unimed Disposable and Reusable SpO2 Sensors are a family of oximeter sensors 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 sensor housing. 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.

Four types of sensor housings are described in this submission:

- Reusable soft tip sensor comprised of an integrated silicone rubber tip.
- Reusable finger clip sensor with rigid halves and silicone pads
- Disposable non- adhesive sensor with sponge and velcro backing.
- Disposable adhesive sensors constructed of a medical tape laminate.

Each sensor has unique labeling and specifications designed for compatibility with the specific monitor (Nellcor, Nonin, BCI, Ohmeda),please refer to the following table:

Compatible monitor model	SPO2 sensor model	Compatible monitor model	SPO2 sensor model
Nellcor NBP-40	U403S-01, U403-01 , U103-01, U103S-01, U543-01, U503-01 N543-01	Masimo Radical RDS-1	U403-125
Ohmeda 3800	U410-03	BCI 3301	U403-06
Nonin 8500	U403-08	Ohmeda 3800	U403-07

8. Intended use

Unimed Disposable and Reusable SPO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate(PR) for adult patients weighing greater than40kg, pediatric patients weighing 10 -50 kg, and neonatal patients weighing no less than 3 Kg.

9. Comparison to predicate device

The Unimed Disposable and Reusable SpO2 Sensors utilize the same measurement principles as the listed predicate devices: two wavelengths of light (red, infrared) from light emitting diodes (LED's) illuminate the patients arterial tissue; and the light transmission through the tissue is measured using a photodiode light detector. The transmission properties vary with the patient's arterial blood saturation and pulse rate.

This method is fundamental to all pulse oximeter sensors and monitors for the non-invasive measurement of functional oxygen saturation (SpO2).

10. Non-clinical test data

The subject device meets the following the recognized standards:

- IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety, 2005
- IEC 60601-1-2 Medical Electrical Equipment-Part 1-2: General Requirements for Safety -Collateral Standard: Electromagnetic Compatibility-Requirements and Tests, 2007
- ISO 80601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 10993-5, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity, 2010

11. Clinical test data

Clinical testing has been performed under an approved protocol with subject informed consent. Clinical hypoxia test results were obtained in human adult volunteers to validate the accuracy of Unimed Disposable and Reusable SPO2 Sensors versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

12. Substantial Equivalence Statement

Based on the comparison ,analysis, and the submitted performance data, Unimed believes that the Unimed Disposable and Reusable SPO2 Sensors are as safe and effective and are substantially equivalent to the predicate devices.