June 5, 2018

Shenzhen Greatmade Tech limited
Mei Mei
QA Manager
3th floor, B building, BaiFuli Industrial Zone
ShangHengLang, HuaHui Road
Shenzhen, CN

Re: K173045
Trade/Device Name: S_pO_2 Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: April 26, 2018
Received: April 30, 2018

Dear Mei Mei:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173045

Device Name
SpO2 Sensor

Indications for Use *(Describe)*
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 at hospital facilities.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 6 510(K) Summary

1. Prepared Date: 2018/2/24

2. Submitter Information

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3. Contact Person

Contact person	Mei
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4. Proposed Device Information

Trade Name	SpO2 Sensor
Model	AF009，AS009，AF063，AS063，AF024-1，AS024-1，DS024-NB
Common name	Oximeter
Regulatory class	Ⅱ
Production regulation	21 CFR §870.2700
Product code	DQA
Panel	Cardiovascular

5. Predicate Device Information

510(K)No.	Trade Name/model	Submitter
K142832	Unimed Disposable And Reusable Spo2 Sensors	Unimed Medical Supplies Inc.

6. Device description

The SpO2 Sensors are a family of oximeter sensors designed for compatibility with listed predicate oximeter manufacturers/monitors. The sensors are made up of connector, cable, two specific wavelength LEDs & a photo detector assembled into the sensor housing. The sensors use optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter. The Sensors contain finger clip type, soft tip and textile adhesive type.
All the sensors will be labeled for compatibility for a specific monitor.

7. Operation principle& Mechanism of action

The SpO2 Sensors will connect with a compatible patient monitor or a pulse oximeter to continuously, non-invasively monitor the functional arterial oxygen saturation (SpO2) of the patient under stationary state.
The SpO2 measurement is based on the absorption of pulse blood oxygen to red and infrared light by means of sensor and SpO2 measuring unit(Pulse Oximeter). The light-electronic transducer in sensor converts the pulse red and infrared light modulated by pulse blood oxygen into electrical signal, the signal is processed by hardware and software of SpO2 measuring unit(Pulse Oximeter). The pleth curve or(and) numeral value of SpO2 will be obtained.

8. Key electrical components description

Spo2 sensor is made up of connector, cable, two specific wavelength LEDs & a photo detector. LED & photo detector are the key electrical components to the subject device. The LED is with wavelength Red:660-666/Infrared:880-950m. The minimum breakdown voltage photo detector is 20V and its response time is 50ns.

9. Indications for use

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 at hospital facilities.

10. Comparison to predicate device

A comparison of key similarities and differences between the subject devices and the predicate devices (K142832) is provided below

Comparison item	Subject Device	Predicate Device K142832	Note
Intended use& Indications for Use	Spo2 sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate(PR) for adult	Unimed Disposable and Reusable SPO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin	Similar

Comparison item	Subject Device	Predicate Device K142832	Note
	patients weighing greater than 40kg,.	(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 .	
Measurement Method	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	Same
Light Emitting	Red:660-666nm, Ired:880-950nm	Red:660-666nm, Ired:880-950nm	same
Signal Detection Method	Photodetector	Photodetector	Same
SPO2 Accuracy	±3%(70-100%)	±3%(70-100%)	Same
Pulse Rate Accuracy	±3(30-250bpm)	±3(30-250bpm)	Same
Applied population	Adult(≥40Kg)	Adult(≥30Kg)&Pediatric(10-50Kg)	Similar
Measurement part	Fingers	Fingers or toes	Similar
compatible monitor	Nellcor(N395) Ohmeda3800	Nellcor(N395) Ohmeda3700	Similar
Sterility	No	No	Same
Usage	Reusable&disposable	Reusable&disposable	Same
Material	ABS,PVC,TPU,Silicone,3M	ABS,PVC,TPU,Silicone,3M	Same
Cable Length	3.0/1.0 m	3.0/1.1m	Similar
Proximal connector Design	DB9 9pin&Round-head 7pin/8p	DB9 9pin&Round-head 7pin/8p	Same
Distal connector Design	finger clip , soft tip, textile adhesive	finger clip , soft tip, textile adhesive and sponge adhesive	Similar
Conformance standard	IEC 60601-1 ,IEC 60601-1-2, ISO 80601-2-61, ISO 10993-5/10	IEC 60601-1 ,IEC 60601-1-2, ISO 80601-2-61, ISO 10993-5/10	Same

From the comparison form above, both devices have the same Measurement Method, Light Emitting, Signal Detection Method, Sterility, Usage & Conformance standard. There are slightly differences between the subject devices and predicate devices as follows.

Difference clause	Discussion
Intended use& Indications for Use & Applied population	The subject device is intended use for adult patients weighing greater than 40Kg. The predicate device, which includes 12 models, is intended for adult, pediatric and neonate patients. but both devices are compatible with the same monitor. This difference does not raise different questions of safety and effectiveness.
Measurement part	The subject devices are intended to be used on fingers not toes; the predicate devices will be applied for fingers and toes. But the spo2 and PR accuracy of subject device applied for fingers meets the requirements of ISO 80601-2-61. This difference does not raise different questions of safety and effectiveness.
compatible monitor	The subject devices is compatible with Nellcor(N395) and Ohmeda3800 monitors. The predicate devices is compatible with Nellcor(N395) and Ohmeda3700 monitors. This difference does not raise different questions of safety and effectiveness.
Cable Length	According to the clinical requirements, the subject device's cable length were designed to be 1.0m & 3.0m. The predicate device's cable lengths are 1.1m & 3.0m. This difference does not raise different questions of safety and effectiveness. Meanwhile the subject device has passed the IEC60601-1, IEC 60601-1-2 and ISO 80601-2-61.
Distal connector Design	The spo2 sensor in this submission have 3 types (finger clip , soft tip &3M). The predicate device has an additional connector of sponge adhesive. This difference does not raise different questions of safety and effectiveness. This subject devices have passed the IEC 60601-1, IEC 60601-1-2and ISO 80601-2-61.

11. Summary of Biocompatibility test

According to IFU, the sensor end will contact with patient finger skin. This submission have three types of sensor housings (soft tip，finger clip & Non-woven) and its duration contact time is less than 2 hours.

The Nature of body contact is skin surface. And the contact duration is less than 24 hours. According to Table 1 - Initial evaluation tests for consideration in ISO 10993-1, the applicable tests are:

- Cytotoxicity
- Sensitization
- Irritation / Intracutaneous

12. Summary of Non-clinical test data

Non clinical tests as follows were conducted to verify that the proposed device met all design specifications to demonstrate Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with requirements of the recognized standards and IFU.

a) Biocompatibility test

b) Testing/ANSI/AAMI/IEC60601-1

c) Testing /ANSI/AAMI/IEC60601-1-2

d) Testing /ISO80601-2-61

e) Cleaning and Disinfection Validation test

f) Shelf life test

g) Performance test for sensors connecting with compatible monitors

h) Pulse rate accuracy test

13. Clinical test data

Clinical testing has been performed under an approved protocol with subject informed consent. Clinical hypoxia test results were obtained in 13 human adult volunteers to validate the accuracy of Spo2 Sensors versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

14. Substantial Equivalence Statement

Based on the comparison, analysis, and the submitted performance data, Spo2 Sensors are as safe, as effective and performs as well as or better

than the predicate device and thus can be considered substantially equivalent to the predicate devices.