Shenzhen Upnmed Equipment Co., Ltd.
Fu Jian
Management Representative
4th Floor, Building #1 East, Huihuang Industrial Area
Xitian Community, Gongming Town, Guangming District
Shenzhen, 518107 Cn

Re: K183277
Trade/Device Name: SpO2 Sensor U401-A, U401-B, U401-C, U401-D
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: April 8, 2019
Received: April 16, 2019

Dear Fu Jian:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K183277

Device Name
SpO2 Sensor, models U401-A, U401-B, U401-C, U401-D

Indications for Use *(Describe)*

This SpO2 Sensor is intended for the continuous noninvasive monitoring and spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR, measured by an SpO2 sensor) for use with the finger of adult and pediatric patients. It acts as re-usable accessory of a Patient Monitor.

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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510(k) Summary

K183277

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:

Shenzhen Upnmed Equipment Co., Ltd.

4th Floor, Building #1 East, Huihuang Industrial Area, Xitian Community, Gongming Town, Guangming District, 518107, Shenzhen, P.R. China

Tel.: +86 -755-29728789
Fax: +86 -755-29423789

Contact Person: Fu Jian

Prepare date: 2019-04-08

2. Device name and classification:

Device Name: SpO_2 Sensor

Models: U401-A, U401-B, U401-C, U401-D

Classification Name: 21 CFR 870.2700 Oximeter

Product code: DQA

Regulatory Class: Class II

3. Reason for Submission

New Application.

4. Predicate Device(s):

Shenzhen Med-link Electronics Tech Co., Ltd., Shenzhen Med-Link Pulse Oximeter Probe, model S0136J-L/ K113727

5. Device Description:

The SpO_2 Sensor consists of compatible connectors, cable, patient side sensor. And one side of sensor is designed to locate light emitting diodes (LEDs) and a light detector (called a photo-detector). Red and Infrared lights are shone through the tissues from one side of the probe to the other. Then parts of the light emitted absorbed by blood and tissues. The light absorbed by the blood varies with the oxygen saturation of haemoglobin. After that, the photo-detector detects the light volume transmitted through the tissues which depends on blood pulse, Hereafter, the microprocessor calculates a value for the oxygen saturation (SpO_2).

The U401 series SpO_2 Sensor acts as re-usable accessory of Mindray PM-8000 Express Patient Monitor, which has been cleared by K070791. And the function alarms and interface accessories are controlled by the monitor, and such information is not available in this submission.

6. Indications for Use:

This SpO2 Sensor is intended for the continuous noninvasive monitoring and spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR, measured by an SpO2 sensor) for use with the finger of adult and pediatric patients. It acts as re-usable accessory of a Patient Monitor.

7. Predicate Device Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness as the predicate device.

Please refer to following table to find differences between the subject device and predicate device. All the differences do not affect the basic design principle, usage, effectiveness of the subject device. And the differences do not raise different questions of safety of effectiveness.

Table 1 Comparison between main predicate S0136J-L and the subject device

ITEM	**Proposed Device U401 Series SpO2 Sensor**	**Predicate Device S0136J-L /K113727**	**Comparison Result**
Manufacture	Shenzhen Upnmed Equipment Co., Ltd.	Shenzhen Med-link Electronics Tech Co., Ltd.	---
Indications for Use	This SpO_2 Sensor is intended for the continuous noninvasive monitoring and spot-checking of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR, measured by an SpO_2 sensor) for use with adult and pediatric patients.	Shenzhen Med-link disposable probe, model S0136J-L, is indicated for single patient use when continuous, non-invasive arterial oxygen saturation and pulse rate monitoring are required for adult patients or pediatric patients weighing more than 30 kg. The S0136J-L is contraindicated for use with patients during motion condition.	Different [1]
Operational Specifications			
Intended patient population	Pediatric, Adult	Pediatric, Adult	Same
Intended application site	Finger	Finger	Same
use under motion and low perfusion conditions	No	No	Same
Measurement Principles	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	Same
Light Emitting Diodes (LEDs) wavelengths	RED: 660 nm, nominal IRED: 905nm, nominal	RED: 660 nm, nominal IRED: 905 nm, nominal	Same
Signal Detection Method	Photodetector	Photodetector	Same
SpO_2 Range	70% -100%	70%-100%	Same
SpO_2 Accuracy	±2%	±3%	Different [2]
Pulse Rate Range	20 bpm – 250 bpm	20 bpm – 250 bpm	Same

Pulse Rate Accuracy	±2 bpm	±3 bpm	Different
Measuring Mode	spot-checking or continuous monitoring	spot-checking or continuous monitoring	Same
Shipped Sterile	No	No	Same
Storage and Transport	Temperature: -10℃to 50℃ Atmospheric Pressure: 50 kPa to l06 kPa Relative Humidity: ≤93% (no condensation)	Temperature: -10℃to 40℃ Atmospheric Pressure: 86 kPa to l06 kPa Relative Humidity: 0%-80% (no condensation)	Different [3]
Operating Temperature	Temperature: 5℃to 40℃ Atmospheric Pressure: 50 kPa to l06 kPa Relative Humidity: ≤85% (no condensation)	Temperature: -10℃to 40℃ Atmospheric Pressure: 86 kPa to l06 kPa Relative Humidity: 0%-80% (no condensation)	
Physical Specifications			
Cable Length	1.0 m	0.9 m	Different [4]

Justification for the differences:

1) Different Indications for Use

As indicated in the comparison table, the difference of indications for Use is caused by different language, so the difference do not raise different questions of safety and effectiveness.

2) Different SpO_2 Accuracy

The accuracy of the subject device is ±2%, which of the predicate is ±3%, which means the performance of the subject is better, and such specification is verified per the international standard ISO 80601-2-61, so the different accuracy will be acceptable for the subject probe.

3) Different Storage and Transport

Minor difference to Storage & Transport and operation environments (including Temperature, Atmospheric Pressure and Relative Humidity) for the subject device, but the system has been proved to be safe and effective since the testing was conducted under the suggested environment; Moreover, environment testing data shows the device can work as declared under the suggested conditions. So those changes do not raise different questions of safety and effectiveness.

4) Different Physical Specifications

The subject and the predicate are of different size but proximity. Moreover, such engineering design has been verified during the international standards, so such minor differences do not raise different questions of safety and effectiveness.

As seen in the comparison tables, the subject and predicate devices have same design principle, similar design features and performance specifications. The main differences between the subject and predicate devices are minor, including only the operating/storage environment, cable length which do not raise different questions of safety or effectiveness. Moreover, as demonstrated in the non-clinical, the different technological characteristics do not raise different questions of safety and effectiveness.

8. Performance Testing:

Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

Non-Clinical Data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the SpO_2 Sensor was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, and the results show that the subject device complies with the IEC 60601-1: 2005+CORR. 1 (2006)+CORR. 2 (2007)+AM1 (2012) *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety and the IEC 60601-1-2: 2007 *Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests* standard for EMC.

Bench Testing

Bench testing was conducted and the results show that the subject device complies with the ISO 80601-2-61: 2011 *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of Pulse Oximeter Equipment* standard for performance effectiveness.

Software Verification and Validation Testing

Not applicable, no software is embedded.

Clinical data:

Clinical testing is conducted per *Annex EE Guideline for evaluating and documenting SpO_2 ACCURACY in human subjects* of *ISO 80601-2-6:2011 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.*
The SpO_2 accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies composed of local healthy men and women from age 18 to 55, with variations of skin pigmentations and per FDA's guidance for Pulse Oximeters, darkly pigmented subjects are included in the desaturation study is three.

Summary

Based on the non-clinical performance and clinical data as documented in the device development, the subject devices were found to be as safe and as effective as the predicate device.

9. Conclusion:

Verification and validation testing was conducted on the subject device and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the subject device is substantially equivalent to the predicate device.