



June 22, 2022

Huizhou Xiaoou Technology Co., Ltd.  
Xia Wang  
General Manager  
3rd Floor, No.113 (Building D), Xikeng Industrial Zone  
Zhongkai High-tech Zone  
Huizhou, Guangdong 516000  
China

Re: K212665

Trade/Device Name: Pulse Oximeter (Model Number-SO611), Pulse Oximeter (Model Number-SO711), Pulse Oximeter (SO811), Pulse Oximeter (SO911)

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: Class II

Product Code: DQA

Dated: May 15, 2022

Received: May 23, 2022

Dear Xia Wang:

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 and Part 809); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney  
Assistant Director  
DHT1C: Division of 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

## Indications for Use

510(k) Number (if known)  
K212665

Device Name  
Pulse Oximeter, Models SO611, SO711, SO811 and SO911

Indications for Use (Describe)

The Pulse Oximeter is intended for spot-checking oxygen saturation and pulse rate, and the device is a reusable device and intended to be used with the finger of adults in professional healthcare facility or home conditions when physician follow-up and operated by a physician. And it is not intended to be used under motion or low perfusion scenarios.

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.**

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# 510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

- 1. Submitter:** Huizhou Xiaouu Technology Co., Ltd.  
3rd Floor, No.113(Building D), Xikeng Industrial Zone, Zhongkai High-tech Zone,  
Huizhou, Guangdong, Shenzhen, 516000, P.R. China  
TEL: +86 752-3302188
- Contact Person:** Xia Wang
- Prepare date:** 2022-04-30
- 2. Device name and classification** **Device Name:** Pulse Oximeter  
**Models:** SO611, SO711, SO811 and SO911  
**Classification Name:** 21 CFR 870.2700 Oximeter  
**Product code:** DQA  
**Regulatory Class:** Class II  
**Class III Summary and Certification:** Not applicable  
**IVD Classification:** Not applicable
- 3. Reason for Submission** New Application. No prior submission associated with the current submission.
- 4. Predicate Device(s)** Shenzhen Yimi Life Technology Co., Ltd., YM101/YM201/YM301 Pulse Oximeter / K191430. No recall or medical device report have been happened to the predicate device.
- 5. Device Description** The oximeter consists of probe, electronic circuits, and display and plastic enclosures. And one side of probe is designed to locate light emitting diodes 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<sub>2</sub>).  
The subject device is a reusable device, and need to reprocess as suggested in the user manual after each use. And the device is intended to be used on the finger, and powered by 2\*1.5V AAA battery.
- All the four models included in this submission, which share the same appearance&size, intended use, performance and similar operation. The differences between all the models is the sound beep and displayed font colors. Sound beep is available for SO811 only, not available for other devices. Regarding the displayed font colors, SO611 and SO711 can show fonts in blue or yellow respectively without multiple colors, while SO811 and SO911 can show the fonts in green/yellow/blue three colors. And the sound beep difference is realized by removing the component buzzer, and the font color difference is realized by minor differentiate the software. Therefore, it can be concluded that all the models share the similar hardware and software in this submission.
- 6. Indications for Use** The Pulse Oximeter is intended for spot-checking oxygen saturation and pulse rate, and the device is a reusable device and intended to be used with the finger of adults in professional healthcare facility or home conditions when physician follow-up and operated by a physician. And it is not intended to be used under motion or low perfusion scenarios.

## 7. Predicate Device Comparison

Please refer to following table to find differences between the subject device and predicate device.

Table 1 Comparison between the predicate and the subject devices

ITEM	Predicate Device YM 101/YM201/YM301 Pulse Oximeter K191430	Proposed Device Pulse Oximeter SO611/SO711/ SO811/SO911	Comparison Result
Manufacture	Shenzhen Yimi Life Technology Co., Ltd.	Huizhou Xiaoou Technology Co., Ltd.	---
Indications for Use	The pulse oximeter is a reusable device and intended for spot-checking of oxygen saturation and pulse rate for use with the finger of adult patients in healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.	The Pulse Oximeter is intended for spot-checking oxygen saturation and pulse rate, and the device is a reusable device and intended to be used with the finger of adults in professional healthcare facility or home conditions when physician follow-up and operated by a physician. And it is not intended to be used under motion or low perfusion scenarios.	Different
Intended patient population	Adult	Adult	
Contraindications	Not intended to be used under motion or low perfusion scenarios.	Not intended to be used under motion or low perfusion scenarios.	Same
<b>Operational Specifications</b>			
Intended application site	Finger	Finger	Same
Measurement Principles	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	Same
Signal Detection Method	Photodetector	Photodetector	Same
Display content	SpO2%, PR, battery indicator, Pulse rate bar graph, pulse waveform	SpO2%, PR, battery indicator, Pulse rate bar graph, pulse waveform	Same
SpO <sub>2</sub> Range	0%~100%, of which effective measurement range is 70%~100%	0 %~100%, of which effective measurement range is 70%~100%	Same
SpO <sub>2</sub> Accuracy	70~100%: ±2% 0% to 69%: unspecified	70% ~100%:±2%; 0% to 69%: unspecified	
SpO <sub>2</sub> Resolution	1%	1%	Same
Pulse Rate Range	25 bpm ~ 250 bpm	30 bpm ~ 250 bpm	Different
Pulse Rate Accuracy	±2 bpm	±3 bpm	
Pulse Rate Resolution	1 bpm	1 bpm	Same
Data Memory	Not available	Not available	Same

Shipped Sterile	No	No	Same
Power supplier	2*1.5V AAA alkaline battery	2*1.5V AAA alkaline battery	Same
Safety classification	Class IIa, Internally powered, Type BF applied part, IP22	Class IIa, Internally powered, Type BF applied part, IP22	Same
Storage and Transport Environment	Temperature: -20°C to 60°C Atmospheric Pressure: 50 kPa to 107.4 kPa Relative Humidity: 10%-95% (no condensation)	Temperature: -10°C to 40°C Atmospheric Pressure: 50 kPa to 106 kPa Relative Humidity: <95% (no condensation)	Different
Operating Environment	Temperature: 15°C to 40°C Atmospheric Pressure: 70 kPa to 106 kPa Relative Humidity: 15%-95% (no condensation)	Temperature: 5°C to 40°C Atmospheric Pressure: 86 kPa to 106 kPa Relative Humidity: 15%-80% (no condensation)	
<b>Compliance Standards</b>			
Bio-compatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	
EMC	IEC 60601-1-2	IEC 60601-1-2	
Performance	ISO 80601-2-61	ISO 80601-2-61	

As seen in the comparison tables, the subject and predicate devices have same design principle, similar design features and performance specifications. The different technological characteristics between the subject and predicate devices will not raise different questions of safety or effectiveness.

## **8. Performance Testing**

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

### **Non-Clinical Testing:**

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

#### **Biocompatibility testing**

The biocompatibility evaluation for the Pulse Oximeter 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 testing included the following tests, results of which demonstrate the biocompatibility of the subject device:

- 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/A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* and *IEC 60601-1-11: 2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* for safety and the *IEC 60601-1-2: 2014 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: 2017 *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of Pulse Oximeter Equipment* standard. And Pulse Rate Accuracy meets the requirements defined in ISO 80601-2-61, Clause 201.12.1.104.

### **Software Verification and Validation Testing**

Software documentation including verification & validation was provided in accordance with FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* for software with a moderate level of concern.

### **Cleaning Validation**

Cleaning and disinfection validation testing was conducted in accordance with FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” issued March 17, 2015. Moreover, the performance of the subject device shows no degradation after repeated cleaning and disinfection as suggested in the manual.

### **Clinical data:**

Clinical testing is conducted per *Annex EE Guideline for evaluating and documenting SpO<sub>2</sub> ACCURACY in human subjects of ISO 80601-2-61:2011 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*. There are 13 healthy volunteers aged between 18 - 50 years old were selected in this study, of which includes 8 females and 5 males, 3 light skin subjects and 3 dark skin subjects. The demographic statistical indicators of the subjects is show in the table below. And no adverse effects and complications happened during the clinical study.

	N	Average mean, S <sub>d</sub>	Minimal	Maximum
Age (year)	13	30.15±11.25	18	50
Height (cm)	13	166±9.61	150	180
Weight (kg)	13	63.04±12.39	47	89

The arm, hand or finger moves may affect the accuracy of SpO<sub>2</sub> measurement, while the gender, age and finger size have no effect to the accuracy of SpO<sub>2</sub> measurement, as the skin pigmentation, in this study, the statistical shows no effect to the safe and effective performance of the oximeter.

### **9. Conclusion**

Verification and validation testing was conducted on the subject device Pulse Oximeter and all testing passed pre-specified criteria. The subject device and the predicate device have the same intended use, and the difference in technological features do not raise different questions of safety and effectiveness. This premarket notification submission demonstrates that the subject device is substantially equivalent to the predicate device.