December 7, 2020

Shenzhen Raysintone Technology CO., Ltd
Xingbao Yang
General Manager
Zone C, 4th Floor, F Building, Xinwei Second Industrial Zone
Guangming District
Shenzhen, Guangdong 518106
China

Re: K201384
Trade/Device Name: Fingertip Pulse Oximeter - models M130, M130A, M130B, M130C, M160A, M160C M170A, M170C, M230, M230A, M230B and M230C
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 1, 2020
Received: November 9, 2020

Dear Xingbao Yang:

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/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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant 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)*
K201384

Device Name
Fingertip Pulse Oximeter, models M130, M130A, M130B, M130C, M160A, M160C M170A, M170C, M230, M230A, M230B and M230C

Indications for Use *(Describe)*
The Fingertip Pulse Oximeter is a reusable non-invasive device intended for the spot checking of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult patients in hospital and other healthcare environments. 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:

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TEL: +86 755 27407409

Contact Person: Xingbao Yang

Prepare date: 2020-11-01

2. Device name and classification

Device Name: Fingertip Pulse Oximeter

Models: M130, M130A, M130B, M130C, M160A, M160C, M170A, M170C, M230, M230A, M230B and M230C

Classification Name: 21 CFR 870.2700 Oximeter

Product code: DQA

Regulatory Class: Class II

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 Pulse Oximeter / K191430

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_2).
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.

M230, M230A, M230B and M230C display the measuring results on 1.3" LED screen, and the screen of M130, M130A, M130B, M130C, M160A, M160C, M170A and M170C are 0.96" OLED. The configuration of the models is shown in the table below.

Function	**M230, M230A, M230B, M230C**	**M130, M130A, M130B, M130C, M160A, M160C, M170A, M170C**
Display	LED	OLED
Spo2 parameter	Yes	Yes

measurement		
Pulse rate measurement	Yes	Yes
Bar graph display	Yes	Yes
Battery display	Yes	Yes
Automatic power-off function	Yes	Yes
Pulse beat sound	No	Yes
Sound On/Off function	No	Yes
Pulse waveform display	No	Yes
Direction display	2	4
Data Record	No	Yes

Scientific concepts that form the basis for the device
Pulse oximeter sensors have red and infrared low voltage light emitting diodes which serve as light sources. The emitted light is transmitted through the tissue, then detected by the photodetector and sent to the microprocessor of the pulse oximeter. All constituents of the human body, venous and arterial blood, and tissue absorb light. The pulsating of arterial blood results in changes in the absorption to added hemoglobin (Hb) and oxygenated hemoglobin (HbO2) in the path of the light. Since HbO2 and Hb absorb light to varying degrees, this varying absorption is translated into plethysmographic waveforms at both red and infrared wavelengths. The relationship of red and infrared plethysmographic signal amplitude can be directly related to arterial oxygen saturation.

Significant physical and performance characteristics of the device, please refer to the column **Proposed Device** in Table 1 for details.

6. Indications for Use

The Fingertip Pulse Oximeter is a reusable non-invasive device intended for the spot checking of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult patients in hospital and other healthcare environments. 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 Pulse Oximeter K191430	Proposed Device M130, M130A, M130B, M130C, M160A, M160C M170A, M170C,M230, M230A, M230B, M230C	Comparison Result
Manufacture	Shenzhen Yimi Life Technology Co., Ltd.	Shenzhen Raysintone Technolog 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 Fingertip Pulse Oximeter is a reusable non-invasive device intended for the spot checking of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult patients in hospital and other healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.	Different
Contraindications	Not intended to be used under motion or low perfusion scenarios.	Not intended to be used under motion or low perfusion scenarios.	Same
Operational Specifications			
Intended patient population	Adult	Adult	Same
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	YM101: SpO2%, PR, battery indicator, Pulse rate bar graph	M230/M230A/M230B/M230C: SpO2%, PR, battery indicator, Pulse rate, bar graph	Same
	YM201: SpO2%, PR, battery indicator, Pulse rate bar graph，pulse waveform	M130/M130A/M130B/M130C/M160A/M160C/M170A/M170C: SpO2%, PR, battery indicator, Pulse rate, bar graph，pulse waveform, Setting item, Data Graphic	Different
SpO_2 Measurement Range	0%~100%	0%~100%	Same
SpO_2 Resolution	1%	1%	Same
SpO_2 Accuracy	70~100%: ±2% 0% to 69%: unspecified	80 to 100%: ±2% 70 to 80%: ±3% 0% to 69%: unspecified.	Different
Pulse Rate Range	25 bpm ~ 250 bpm	25 bpm ~ 254 bpm	Different
Pulse Rate Accuracy	±2 bpm	±3 bpm	
Pulse Rate Resolution	1 bpm	1 bpm	Same
Shipped Sterile	No	No	Same
Power suppler	2*1.5V AAA alkaline battery	2*1.5V AAA alkaline battery	Same

Storage and Transport Environment	Temperature: -20℃to 60℃ Atmospheric Pressure: 50 kPa to l07.4 kPa Relative Humidity: 10%-95% (no condensation)	Temperature: -20℃to 60℃ Atmospheric Pressure: 50 kPa to l07.4 kPa Relative Humidity: 10%-95% (no condensation)	Same
Operating Environment	Temperature: 15℃to 40℃ Atmospheric Pressure: 70 kPa to l06 kPa Relative Humidity: 15%-95% (no condensation)	Temperature: 15℃to 40℃ Atmospheric Pressure: 70 kPa to l06 kPa Relative Humidity: 15%-95% (no condensation)	
Compliance Standards			
Bio-compatibility	ISO 10993-1 ISO 109903-5 ISO 10993-10	ISO 10993-1 ISO 109903-5 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	
Physical Specifications			
Dimension (Width*Height*Depth)	57mm×30mm×30 mm	M230,M230A,M230B,M230C,M130,M130A,M130B,M130C: 57.5mm×32.5mm×32mm M160A,M160C,M170A,M170C: 64mm×38.5mm×36.5mm	Different
Weight	<28 g (without the batteries)	M230,M230A,M230B,M230C,M130,M130A,M130B,M130C: Approx: 49g (including the batteries) M160A,M160C,M170A,M170C: Approx: 62g (including the batteries)	

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 Fingertip 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+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. 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_2 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.*

9. Conclusion

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