October 18, 2019

Shenzhen Yimi Life Technology Co.,Ltd.
Shande Peng
General Manager
305 Tengbo Industrial Park, Changshangjiang Street,
Longbei Village, Pingshan District
Shenzhen, 518118 CN

Re: K191430
Trade/Device Name: Pulse Oximeter, models YM101, YM201, YM301
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 10, 2019
Received: September 20, 2019

Dear Shande Peng:

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,

for 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)*
K191430

Device Name
Pulse Oximeter, models YM101, YM201, YM301

Indications for Use *(Describe)*

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.

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

K191430

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:	Shenzhen Yimi Life Technology Co., Ltd. 305 Tengbo Industrial Park, Changshangjiang Street, Longbei Village, Pingshan District, 518118, Shenzhen, P.R. China Tel.: +86 755- 86573112
Contact Person:	Shande Peng
Prepare date:	2019-10-17
2. Device name and classification	**Device Name:** Pulse Oximeter **Models:** YM101, YM201, YM301 **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 IMDK Medical Technology Co., Ltd., C101H1 Pulse Oximeter / K173123
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. YM101 display the measuring results on 1.5' LED screen, and the backlight of the three models are red, white and green respectively. And the screen of YM201 and YM301 are 0.96' OLED and 1.3' OLED. Additionally, battery indicator and pulse waveform can be displayed on YM201 and YM301.
6. 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.

7. Predicate Device Comparison

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

Table 1 Comparison between main predicate C101H1 and the subject device

ITEM	Proposed Device YM series Pulse Oximeter	Predicate Device C101H1/K173123	Comparison Result
Manufacture	Shenzhen Yimi Life Technology Co., Ltd.	Shenzhen Med-link Electronics Tech Co., Ltd.	---
Indications for Use	The pulse oximeter is intended for measure oxygen saturation and pulse rate of adult patients in healthcare environments.	Fingertip Pulse Oximeter C101H1 is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in hospitals.	Different
Operational Specifications			
Intended patient population	Adult	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
Signal Detection Method	Photodetector	Photodetector	Same
SpO_2 Range	0~100%	0~100%	Same
SpO_2 Resolution	1%	1%	Same
SpO_2 Accuracy	70~100%: ±2% 0% to 69%: unspecified	70~100%: ±3% 0% to 69%: unspecified	Different
Pulse Rate Range	25 bpm ~ 250 bpm	30 bpm ~ 240 bpm	Different
Pulse Rate Accuracy	±2 bpm	±1 bpm or ±1%, whichever is greater	
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: -10℃to 40℃ Atmospheric Pressure: 70 kPa to l06 kPa Relative Humidity: 10%-80% (no condensation)	Different

Operating Environment	Temperature: 15℃to 40℃ Atmospheric Pressure: 70 kPa to l06 kPa Relative Humidity: 15%-95% (no condensation)	Temperature: 5℃to 40℃ Atmospheric Pressure: 70 kPa to l06 kPa Relative Humidity: 15%-80% (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	60mm×35mm×35 mm	Different

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+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 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.