DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 19, 2017

Shenzhen Fitfaith Technology Co.,ltd
% Migo. Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1122#, Internation Mayor Communication Center,
Baishizhong Rd 55#,
Nanshan District, Shenzhen, 518000 CN

Re: K163135
Trade/Device Name: Fingertip Pulse Oximeter (Model: A300, A310, M110, M120, M130, M150, M160, M170, M230)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 15, 2017
Received: August 7, 2017

Dear Migo. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163135

Device Name
Fingertip Pulse Oximeter (Model: A300, A310, M100, M110,M120,M130,M150,M160,M170,M230)

Indications for Use *(Describe)*
The Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The portable fingertip device is indicated for adult and pediatric patients in home and hospital environments (including clinical use in internist/ surgery, anesthesia, intensive care, etc).

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

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Submission Date	Aug 18,2016
Manufacturer information	Submitter's Name: Shenzhen Fitfaith Technology Co.,Ltd. Address: Area B, Floor 9, Building D1, Tangwei Industrial Park, Donglong Road, Guangming New District, ShenZhen, Guangdong, China. Contact person: Yuan.Junfeng TEL: +86-0755-29544253-803 FAX: +86-0755-29544253-801 E-Mail: 160666@qq.com
Submission Correspondent	Contact person: Miss Migo.Yang E-Mail: migo@cefda.com Shenzhen Joyantech Consulting Co., Ltd. 1122#，International Mayor Communication Center, Baishizhong Road 55#, Nanshan District, Shenzhen, Guangdong, China. Contact person: Mr. Field.Fu E-Mail: cefda13485@163.com Shenzhen Joyantech Consulting Co., Ltd. 1122#，International Mayor Communication Center, Baishizhong Road 55#, Nanshan District, Shenzhen, Guangdong, China
Establishment registration number	NA

2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Fingertip Pulse Oximeter (Model: A300, A310, M100, M110,M120,M130,M150,M160,M170,M230)
Classification name:	Oximeter
Review Panel:	Anesthesiology
Product Code:	DQA
Device Class:	II
Regulation	870.2700
Number:	**K163135**

3 Predicate Device Information

Sponsor:	Shenzhen Jumper Medical Equipment Co., Ltd.
Device:	JPD-500A Fingertip Pulse Oximeter
510(K) Number:	K140582

4 Device Description

The Fingertip Pulse Oximeteris intended for spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of adult and pediatric patients in the home and hospital.

The fingertip pulse oximeter features a small size, low power consumption, a convenient operation, and portability.It is only necessary for a patient to put one of his/her fingers into the fingertip clips for measurement.

Principle of the fingertip pulse oximeter as follows:

A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in red and infrared zones.

Operation principle of the instrument:

Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 905nm infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. Relevant data is shown on the Oximeter’s display through electronic circuits and a microprocessor.

5 Intended Use

The subject device is intended for measuring the functional oxygen saturation and pulse rate (PR) through a patient’s finger. It is applicable for spot-checking SpO2 and pulse rate (PR) of adult and pediatric patients in homes and clinics.

6 Indications for Use

The Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The portable fingertip device is indicated for adult and pediatric patients in home and hospital environments (including clinical use in internist/ surgery, anesthesia, intensive care, etc).

7 Contraindications

- High-frequency electrosurgical
- Placement of a sensor on an extremity with a blood pressure cuff arterial catheter, or intravascular line
- The patient has hypotension severe vasoconstriction severe anemia or hypothermia.
- The patient is in cardiac arrest or is in shock.
- Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

8 SE Comparison

Table 1. Substantial Equivalence Comparison

Characteristics	Subject device	Predicate device (k140582)	Remark
Device name	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter	/
Model	A300,A310,M100,M110,M120,M130,M150,M160,M170,M230 Note: *A300 and M110 are totally identical model except for model name based on customer's requirement; A310 and M100 are totally identical model except for model name based on customer's requirement;*	JPD-500A	/
Manufacturer	Shenzhen Fitfaith Technology Co.,Ltd.	Shenzhen Jumper Medical Equipment Co.,Ltd	/
Intended patient population	Adult & Pediatric	Adult & Pediatric	same
Intended application site	Fingertip		same
Intended Environments	home & hospital		same
Prescription & OTC	Prescription		same
Intended use	The subject device is intended for measuring the functional oxygen saturation and pulse rate through patient's finger. It is applicable for spot-checking SpO2 and pulse rate of adult and pediatric patients in homes and clinics.		same
Indications for Use	The Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The portable fingertip device is indicated for adult and pediatric patients in home and hospital environments (including clinical use in internist/ surgery, anesthesia, intensive care, etc).	The JPD-500A Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (Spo2) and pulse rate. The portable fingertip device is indicated for adult and pediatric patients in home and hospital environments (including clinical use in internist/ surgery, anesthesia, intensive care, etc).	*Similar(Note01)*

Characteristics		Subject device	Predicate device (k140582)	Remark
Working Principle		A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in red and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the Oximeter's display through process in electronic circuits and microprocessor.		same
Light Specification	wavelength	660nm±3nm for red light, 905nm±5nm for infrared light (IR)		same
	maximum optical power	1.5 mW for red light (660nm) 1.2 mW for IR (905nm)		same
Contact Material		ABS for enclosure, silica gel for clip		same
Internal Power supply		2*AAA 1.5v alkaline battery		same
Working Current		Less than 40mA(Normal)	35mA	*Similar(Note02)*
Resolution	SpO2	1%		same
	Pulse rate	1 bpm		same
Measurement Range	SpO2	0%~100%		same
	Pulse rate	25~250 bpm		same
Measurement Accuracy	SpO2	±2%: (70%~100%)	±2%: (70%~100%)	same
		Unspecified : (0%~69%)	no definition(0%~69%)	
	Pulse rate	±2 bpm	±2 bpm	same
Operating Environment	Temperature	5℃~40℃		*Similar (Note03)*
	Humidity	15%~85% non-condensing	15%~80% non-condensing	
Storage & Transport Environment	Temperature	-20℃~+55℃	-10℃~+50℃	*Similar(Note04)*
	Humidity	10%~95%	10%~93%	

Note01:

The trade name is different, but SE determination does not depend on trade name.

Note02:

The working currents of subject device and predicate device are similar. The subject device met the requirements of IEC 60601-1.

Note03:

The humidity under operating environment of subject device and predicate device are similar. The subject device met the requirements of ISO 80601-2-61.

Note04:

The Storage & Transport environment of subject device and predicate device are similar. The subject device met the requirements of ISO 80601-2-61.

The subject device is the same as the predicate device in intended use, intended patient population, intended application site, working principle, contact material, internal power supply, display range, resolution. Only their appearance, indication for use (Note01), working current (Note02), operation environment (Note03), storage transport environment (Note04), are a little bit different. However, the minor differences do not raise different questions of safety and effectiveness.

9 Brief discussions of tests

9.1 Brief discussions of the nonclinical tests

The subject device conforms to the following standards:

- ✧ IEC 60601-1:2005+A1:2012: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- ✧ IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests;
- ✧ IEC 60601-1-11: Requirements for Medical Electrical (ME) Equipment and ME Systems used in the Home Healthcare Environment;
- ✧ ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity;
- ✧ ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;
- ✧ ISO 80601-2-61:2011 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment;
- ✧ Cleaning and low level disinfection validation.

9.2 Brief discussions of clinical tests

Clinical testing according to ISO 14155:2011 and ISO 80601-2-61: 2011 has also been performed on the device.

Clinical hypoxia accuracy testing (controlled desaturation study) was conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark-skinned subjects in an independent research laboratory. The measured arterial

hemoglobin saturation value (SpO2) of the subject device was compared with arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a CO-oximeter (control device). The accuracy of the subject device is in comparison with the control device over the SpO2 range of 70~100%.
Data was calculated and analyzed using the mean bias (B), root-mean-square (A_{rms}), PRECISION (standard deviation of the residuals (s_{res}) for all subjects, per ISO 80601-2-61, the result showed that the error is far less than the scope specified in the ISO 80601-2-61;
Besides, the Agreement between methods of measurement with multiple observations for both all subjects pooled and individual test subjects were analyzed with the Bland and Altman statistics, the analysis demonstrated that the vast majority of data is within ±95% limit of agreement, the data points beyond or below this scope were regarded as outliers. The outliers only occurred occasionally and after being analyzed, it was determined that the outliers do not raise performance concerns regarding the accuracy and precision of the device.
During the clinical study, 12 subjects were enrolled, who are healthy, non-smoking, competent adults, between twenty-one and thirty-two (21-32) years of age, and they were provided EC (Ethics Committee)-approved informed consent as documented on an informed consent form. No case was lost in this trial.
The trial completed 12 cases, on which 294 data sets were collected, of which 288 were valid. 6 data sets which less than 70% were excluded. The result met the criteria specified in the ISO 80601-2-61; In addition, there were no reported adverse effects during these investigations.

10 Other information (such as required by FDA guidance)

No other information.

11 Conclusions

Based on the clinical and non-clinical testing performed, the results demonstrate that the subject device fingertip pulse oximeter is substantially equivalent to the predicate device JPD-500A Fingertip Pulse Oximeter manufactured by Shenzhen Jumper Medical Equipment Co., Ltd.