December 16, 2022

ShenZhen ZhengKang Technology Co., Ltd.
% Becky Chen
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 218, Building 2, Yike Intelligent Innovation Park,
No. 232 Kezhu Road, Huangpu
Guangzhou, Guangdong 510000
China

Re: K213984
Trade/Device Name: Oximeter (Model: JZK-301,JZK-303,JZK-305,JZK-307)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 9, 2022
Received: December 12, 2022

Dear Becky Chen:

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,

James J. Lee -S

James J. Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthsia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213984

Device Name
Oximeter (Model: JZK-301, JZK-303, JZK-305, JZK-307)

Indications for Use *(Describe)*
The 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 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.

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510 (k) Summary

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	ShenZhen ZhengKang Technology Co., Ltd.
Address:	2&3/F, Building A, No. 3 FuXing Yi Lane, HeHua Community, PingHu Street, LongGang District, ShenZhen, GuangDong, China
Contact person:	Huayong Yang
Phone number:	+86-755-83260864
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Email:	893488645@qq.com
Date of summary prepared:	12/14/2022
Reason for the submission:	New device, there were no prior submissions for the device.

(2) Proprietary name of the device

Trade name/model:	Oximeter / JZK-301, JZK-303, JZK-305, JZK-307
Common name:	Oximeter
Regulation number:	21CFR 870.2700
Product code:	DQA
Review panel:	Anesthesiology
Regulation class:	Class II

(3) Predicate device and Reference Device

	Predicate Device	**Reference Device**
Sponsor	Shenzhen Fitfaith Technology Co.,Ltd.	Xuzhou Yongkang Electronic Science Technology Co., Ltd.
Device Name/Model	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter
510(k) Number	K163135	K161938
Product Code	DQA	DQA
Regulation Number	21CFR 870.2700	21CFR 870.2700
Regulation Class	II	II

(4) Description/ Design of device:

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

The 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 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.

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.

The four models (JZK-301, JZK-303, JZK-305, and JZK-307) have the same intended use, working principle, characteristic, and conformance standards, only in appearance have some different (appearance design, dimension, and weight).

(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 patients in homes and clinics.

(6) Indications for Use:

The 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 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) Materials

Test Article Name	Body Contact Category	Contact Duration
Oximeter	Surface skin contact	Prolonged (＞24h to 30d)

We have tested the oximeters and obtained the Biocompatibility test reports. For details, please refer to "Biocompatibility Discussion".

(9) Technological characteristics and substantial equivalence:

Characteristics	Targeted device	Predicate device	Reference device	Remark
Trade name	Oximeter	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter	/
Model	JZK-301, JZK-303, JZK-305, JZK-307 Note: The 4 models have the same technological characteristics, only in appearance have some different.	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	YK-81C	/
Manufacturer	ShenZhen ZhengKang Technology Co., Ltd.	Shenzhen Fitfaith Technology Co.,Ltd.	Xuzhou Yongkang Electronic Science Technology Co., Ltd.	/
510 (k) number	Pending	K163135	K161938	/
Regulation number	21CFR 870.2700	21CFR 870.2700	21CFR 870.2700	Same
Regulation description	Oximeter	Oximeter	Oximeter	Same
Product code	DQA	DQA	DQA	Same
Class	II	II	II	Same
Intended use	The subject device is intended for	The subject device is intended for	The pulse oximeter,	Same. Within

Characteristics	Targeted device	Predicate device	Reference device	Remark
	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 patients in homes and clinics.	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.	YK-81C, is designed for spot checking of the pulse oxygen saturation and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously monitoring.	the range of predicate device. (The predicate device is intended for use by adult and pediatric patient, our device is intended for use by adult patient only.
Indications for use	The 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 patients in home and hospital environments (including clinical use in internist/ surgery, anesthesia, intensive care, etc).	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 pulse oximeter (YK-81C) is designed for spot checking of the pulse oxygen saturation and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously monitoring.	Same. Within the range of predicate device. (The predicate device is intended for use by adult and pediatric patient, our device is intended for use by adult patient only.
Intended patient population	Adult	Adult & Pediatric	Adult	Same with

Characteristics	Targeted device	Predicate device	Reference device	Remark
				reference device; Within the range of predicate device.
Intended application site	Fingertip	Fingertip	Fingertip	Same
Intended environments	Home & hospital	Home & hospital	Clinic	Same with predicate device
Prescription & OTC	Prescription	Prescription	Prescription	Same
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	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	/	Same

Characteristics	Targeted device	Predicate device	Reference device	Remark
	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.	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.		
Wavelength	Red light: 660nm±3nm Infrared light: 905nm±5nm	Red light: 660nm±3nm Infrared light: 905nm±5nm	Red light: 660nm Infrared light: 940nm	Same with predicate device
Maximum optical power	21.8 mW for red light (660nm) 5 mW for IR (905nm)	1.5 mW for red light (660nm) 1.2 mW for IR (905nm)	21.8 mW	Similar Note 1
Contact material	ABS for enclosure silica gel for clip	ABS for enclosure silica gel for clip	/	Same
Internal Power supply	DC 3V (two AAA alkaline batteries)	2*AAA 1.5v alkaline battery	2 AAA alkaline batteries	Same
Working current	Less than 40mA(Normal)	Less than 40mA(Normal)	/	Same
Resolution	SpO2: 1% Pulse rate: 1 bpm	SpO2: 1% Pulse rate: 1 bpm	SpO2: 1% Pulse rate: 1 bpm	Same
Measurement range	SpO2: 45-100% Pulse rate: 25-250 bpm	SpO2: 0-100% Pulse rate: 25-250 bpm	SpO2: 0-100% Pulse rate: 30-254 bpm	Similar Note 2
Measurement accuracy	SpO2: ±2%: (70%~100%) Unspecified for <70%	SpO2: ±2%: (70%~100%) Unspecified: (0%~69%)	SpO2: ±3%: (70%~100%) Unspecified: (0%~69%)	Same with predicate device
	Pulse rate: ±2 bpm	Pulse rate: ±2 bpm	Pulse rate: ±2 bpm	
Operating environment	Temperature: 5℃~40℃;	Temperature: 5℃~40℃;	/	Similar Note 3

Characteristics	Targeted device	Predicate device	Reference device	Remark
	Humidity: ≦80%RH	Humidity: 15～85%RH (non-condensing)		
Storage and transport environment	Temperature: -20℃~+55℃; Humidity: ≦93%RH	Temperature: -20℃~+55℃; Humidity: 10～95%RH	/	Similar Note 4
Tests	IEC 60601-1 test; IEC 60601-1-2 test; IEC 60601-1-11 test; ISO 80601-2-61 test; ISO 10993-5 test; ISO 10993-10 test; ISO 10993-23 test; Cleaning validation; Clinical accuracy test	IEC 60601-1 test; IEC 60601-1-2 test; IEC 60601-1-11 test; ISO 80601-2-61 test; ISO 10993-5 test; ISO 10993-10 test; Cleaning validation; Clinical accuracy test	IEC 60601-1 test; IEC 60601-1-2 test; IEC 60601-1-11 test; ISO 80601-2-61 test; ISO 10993-5 test; ISO 10993-10 test; Cleaning validation; Clinical accuracy test	Same

Comparison in details:

Note 1:

The value of the maximum optical power of subject device is between predicate device and the reference device. The higher the optical power, the stronger the light and the better the accuracy. This value is small and does not affect safety. The subject device met the requirements of ISO 80601-2-61. Such a difference does not raise new questions of safety and effectiveness.

Note 2:

The measurement range of subject device is within the measurement range of predicate device. The subject device met the requirements of IEC 60601-1 and ISO 80601-2-61. Such a difference does not raise new questions of safety and effectiveness.

Note 3:

The humidity under operating environment of subject device and predicate device are similar. The subject device met the requirements of IEC 60601-1 and ISO 80601-2-61. Such a difference does not raise new questions of safety and effectiveness.

Note 4:

The humidity under storage & transport environment of subject device and predicate device are similar. The subject device met the requirements of ISO 80601-2-61. Such a difference does not raise new questions of safety and effectiveness.

Comparison analysis conclusion:

The subject device has the same technological characteristics as the predicate device. Only their appearance, maximum optical power (Note 1), measurement range (Note 2),

operating environment (Note 3), storage and transport environment (Note 4) are a little bit different. However, the minor differences do not raise safety and effectiveness questions.

(8) Nonclinical and Clinical Tests:

Non-clinical Tests:

The following performance data have been conducted to verify that the Oximeter meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

Biocompatibility Testing:

The biocompatibility evaluation for the oximeter was conducted in accordance with the FDA's Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process'" and per recommendations from the following standards:

- ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-23, Biological Evaluation Of Medical Devices - Part 23: Tests For Irritation

The oximeter has passed the Biocompatibility tests.

Electrical and EMC Safety:

The electrical safety and EMC safety testing was performed to, and passed, the following standards:

- ANSI AAMI ES60601-1 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-11 Edition 2.0 2015-01, 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
- IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral standard: Electromagnetic disturbances - Requirements and tests
- ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02), Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Software:

We have conducted Software verification and validation according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices".

Clean Validation:

We have conducted clean validation according to the requirements of the FDA "Pulse Oximeters – Premarket Notification Submissions [510(k)s] – Guidance for Industry and Food and Drug Administration Staff" to prove that the device can continue to perform as intended after cleaning in accordance with the specific cleaning method.

Clinical Test:

Clinical testing according to ISO 80601-2-61: 2011 has also been performed on the device. Clinical hypoxia accuracy testing was conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark-skinned subjects in an independent research laboratory during non-motion/static conditions. The device is not intended for SpO2 monitoring in conditions of motion or low perfusion. 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 (Arms), PRECISION (standard deviation of the residuals (sres) 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, nonsmoking, competent adults, between 18-50 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 300 data sets were collected, of which 289 were valid. 11 data sets 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.

Summary:

Based on the above nonclinical and clinical tests as documented in this application, the Oximeter was found to have a safety and effectiveness profile that is similar to the predicate device.

(9) Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the Oximeter is to be concluded substantial equivalent to its predicate device.