April 23, 2021

Shenzhen Hexin ZONDAN Medical Equipment Co., Ltd.
John Liu
RA Manager
Floor 14, Block D, Dianlian Technology Building,
the Crossing between South Circle Road and South Fuli Road,
Shenzhen, Guangdong 518106
China

Re: K203854
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 23, 2021
Received: March 23, 2021

Dear John Liu:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203854

Device Name
Pulse Oximeter

Indications for Use *(Describe)*
The 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 21 CFR 807.92.

1. Submitter's Identification

Applicant: Shenzhen Hexin ZONDAN Medical Equipment Co., Ltd.
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Prepared by: Mr. John Liu
Regulatory Manager
E-mail: liuming@zondan.com

Date prepared: Dec. 21, 2020

2. Subject device information

Device Common Name: Oximeter

Device Trade Name: Pulse Oximeter

Model: A2, A3, A4, A5

Regulation Number: 21 CFR 870.2700

Regulation Name: Oxiemter

Regulatory Class: II

Product Code: DQA

3. Predicate device information

510(k) Number: K163135

Trade/ Device Name: Fingertip Pulse Oximeter

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: II

Product Code: DQA

Manufacturer: Shenzhen Fitfaith Technology Co., Ltd.

4. Device description

The Pulse Oximeter 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.

The Pulse Oximeter is as a stand-alone device, which is powered by an internal battery. The device is for multi-use. The device is not for life supporting or life sustaining, not for implant. The device is not sterile, the device is not a reprocessed single-use device, and the device does not contain drug or biological products.

5. Intended Use

The Pulse Oximeter 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. Indication for Use

The 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. Substantial Equivalence Comparison

Characteristics	Subject device	Predicate device (K163135)	Remark
Device name	Pulse Oximeter	Fingertip Pulse Oximeter	NA
Model	A2, A3, A4, A5	A300	NA
Manufacturer	Shenzhen Hexin ZONDAN Medical Equipment Co.,Ltd.	Shenzhen Fitfaith Technology Co., Ltd.	NA
Classification	Class II	Class II	Substantially Equivalent.
Product code	DQA	DQA	Substantially Equivalent.
Prescription or OTC	Prescription	Prescription	Substantially Equivalent.
Intended use	The Pulse Oximeter 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.	The Fingertip Pulse Oximeter 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.	Substantially Equivalent.
Indications for	The Pulse Oximeter is	The Fingertip Pulse	Substantially

use	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).	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).	Equivalent.
Design 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		Substantially Equivalent.

	obtained by a photosensitive element, will be shown on the Oximeter's display through process in electronic circuits and microprocessor.		
Environment of use	Home and Hospital	Home and Hospital	Substantially Equivalent.
Patient type	Adult and Pediatric	Adult and Pediatric	Substantially Equivalent.
Intended application site	Fingertip	Fingertip	Substantially Equivalent.
Type, Degree of protection against electric shock	Internally powered equipment; Type BF applied part.	Internally powered equipment; Type BF applied part.	Substantially Equivalent.
Power supply	2*AAA 1.5V alkaline battery	2*AAA 1.5V alkaline battery	Substantially Equivalent.
Work current	＜40mA	＜40mA	Substantially Equivalent.
Light specification	Wavelength: RED: 660nm±5nm, IR: 905nm±5nm	Wavelength: RED: 660nm±3nm, IR: 905nm±5nm	Substantially Equivalent.
	Maximum optical power: RED: 1.5mW, IR: 1.2mW	Maximum optical power: RED: 1.5mW, IR: 1.2mW	Substantially Equivalent.
SpO2 display range	0%～100%	0%～100%	Substantially Equivalent.
SpO2 measurement	70%-100%, accuracy: ±2%; ＜70%, no definition.	70%-100%, accuracy: ±2%; ＜70%, no definition.	Substantially Equivalent.

accuracy			
SpO2 resolution	1%	1%	Substantially Equivalent.
Pulse rate display range	30bpm～240bpm	25bpm～250bpm	Different Note 01
Pulse rate measurement accuracy	±1bpm	±2bpm	Different Note 02
Pulse rate resolution	1bpm	1bpm	Substantially Equivalent.
Operation environment	Temperature: 5℃ ～ 40℃ Humidity: 30% ～ 80% (non-condensing) Atmospheric pressure: 70kPa ～ 106kPa	Temperature: 5℃ ～ 40℃ Humidity: 15% ～ 85% (non-condensing)	Different Note 03
Storage & Transport environment	Temperature: -20℃ ～ +55℃ Humidity: 10% ～ 93% (non-condensing) Atmospheric pressure: 70kPa ～ 106kPa	Temperature: -20℃ ～ +55℃ Humidity: 10% ～ 95% (non-condensing)	
Contacting material	ABS (Acrylonitrile butadiene styrene copolymers) for enclosure, silicone for clip	ABS (Acrylonitrile butadiene styrene copolymers) for enclosure, silicone for clip	Substantially Equivalent.

Contact duration	＜24h	＜24h	Substantially Equivalent.
Contact type	Skin surface-contacting	Skin surface-contacting	Substantially Equivalent.
Biocompatibility of patient contact parts	Comply with ISO 10993-1	Comply with ISO 10993-1	Substantially Equivalent.

Note 01:

The pulse rate display range of the subject device is different from the predicate device. But the subject device complies with the claimed display range according to bench test report.

Note 02:

The pulse rate measurement accuracy of the subject device is different from the predicate device. But the subject device complies with the claimed measurement accuracy according to bench test report.

Note 03:

The operation and storage & transport environment of subject device are different from predicate device. But the subject device has been verified all the full claimed range according to the IEC 60601-1, IEC 60601-1-11 and ISO 80601-2-61 standards.

Based on the aforementioned substantial equivalence comparison table, the subject device is as same as predicate device. Only Pulse rate display range (refer to Note 01), Pulse rate measurement accuracy (refer to Note 02), Operation and Storage & Transport environment (refer to Note 03) are different which had been validated. However, the differences would not raise any safety and effectiveness issue based on tests in this submission.

Thus, the subject device is substantially equivalent to the predicate device which is

legally marketed in US.

8. Brief discussions of the non-clinical tests

The following tests were conducted to demonstrate substantial equivalence to the predicate device:

Test Standard	Description	Result
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	Pass
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	Pass
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	Pass
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	Pass
ISO 10993-1 Fourth edition 2009-10-15	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]	Pass

ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Pass
ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass
ISO 14971 Second edition 2007-03-01	Medical devices - Application of risk management to medical devices	Pass

It is concluded that the subject device is in compliance with the requirements of the aforementioned tests.

9. Brief discussions of the clinical tests

The functional oxygen saturation (SpO2) measurement has been validated in accordance with ISO 80601-2-61. The clinical testing was completed on healthy, non-smoking, a total of 12 healthy adult volunteers (5 men and 7 women) with light to dark skin pigmentations in the range of 70% to 100% against a laboratory CO-Oximeter. The subjects include 10 with light skin, and 2 with dark skin pigmentation. Total 278 data points were sampled for analysis. The measured arterial hemoglobin saturation value (SpO2) of the proposed device was compared with arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a CO-oximeter. The accuracy of the device is in comparison with the CO-oximeter samples measured over the SpO2 range 70%-100%.

Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, the SpO2 accuracy result showed that the root-mean-square (Arms) value of the Pulse Oximeter is less than ±2% SpO2 over the declared range of 70% to 100%; and the Agreement between Methods of Measurement with Multiple Observations per each subject was analyzed with the Bland and Altman statistics, the analysis demonstrated that the vast majority of data is within ±95% limit of agreement.

10.Software information

The software level of concern for the subject device is MODERATE. According to FDA Guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and FDA Staff”, the software validation documentation summarizes the required information for a MODERATE Level of Concern device.

11.Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Shenzhen Hexin ZONDAN Medical Equipment Co., Ltd. concludes that the subject device is as safe and as effective, and thus substantially equivalent, to the predicate device, A300 Fingertip Pulse Oximeter manufactured by Shenzhen Fitfaith Technology Co., Ltd..