December 30, 2022

Shenzhen Witleaf Medical Electronics Co.,Ltd
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K213430
Trade/Device Name: Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 18, 2022
Received: November 18, 2022

Dear Kevin Wang:

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.
Director
DHT1C: Division of 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)*
K213430

Device Name
Fingertip Pulse Oximeter

Indications for Use *(Describe)*
This Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). It is indicated for adult patients in home and hospital environment. The device is not intended for continuous monitoring, use during motion or use with low perfusion.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2021/11/17

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
E-mail: kevin@chonconn.com
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3. Subject Device Information

Trade/Device Name	Fingertip Pulse Oximeter
Model	WIT-S200, WIT-S400
Common Name	Fingertip Pulse Oximeter
Regulatory Class	Class II
Classification	21CFR 870.2700 / Oximeter / DQA
Submission type	Traditional 510(K)

4. Predicate Device

Manufacturer: Shenzhen Hexin ZONDAN Medical Equipment Co., Ltd
Device name: Pulse Oximeter, A2, A3, A4, A5
510(K) Number: K203854

5. Device Description

The Fingertip Pulse Oximeter is intended for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).

The Fingertip Pulse Oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red

light; the other is 905 nm, which is Infrared light. Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photodetector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2. The Fingertip Pulse Oximeter is powered by 2 AAA batteries.

The device mainly composed of PCB board, one key, OLED&LED screen, battery compartment, and plastic shell. The device is a spot-check Fingertip Pulse Oximeter and does not include alarms. The device is not intended for life-supporting or life-sustaining.

6. Intended use & Indication for use

This Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). It is indicated for adult patients in home and hospital environment. The device is not intended for continuous monitoring, use during motion or use with low perfusion.

7. Comparison to the Predicate Device

Features	**Subject Device** Fingertip Pulse Oximeter WIT-S200, WIT-S400	**Predicate Device K203854** Pulse Oximeter, Model: A2, A3, A4, A5	**Comparison**
Applicant	Shenzhen Witleaf Medical Electronics Co., Ltd.	Shenzhen Hexin ZONDAN Medical Equipment Co., Ltd.	/
Classification Regulation	21CRF 870.2700	21CRF 870.2700	Same
Classification and Code	Class II, DQA	Class II, DQA	Same
Prescription or OTC	Prescription	Prescription	Same
Intended use	This Fingertip Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). It is indicated for adult patients in home and hospital environment. The device is not intended for continuous monitoring, use during motion or use with low perfusion.	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.	Same
Indication for use		The Pulse Oximeter is non-invasive device intended for spot-checking of functional oxygen	Same

Features	**Subject Device** Fingertip Pulse Oximeter WIT-S200, WIT-S400	**Predicate Device K203854** Pulse Oximeter, Model: A2, A3, A4, A5	**Comparison**
		saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The portable fingertip device is indicated for adult and pediatric patients in home and hospital environment(including clinical use in internist/surgery, anesthesia, intensive care, etc.)	
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 obtained by a photosensitive element, will be shown on the Oximeter's display through process in electronic circuits and microprocessor.		Same
Environment of use	Home and Hospital	Home and Hospital	Same
Patient populations	adult	adult or pediatric	different
Motion condition	Not applicable	Not applicable	Same
Perfusion condition	Not applicable for low perfusion	Not applicable for low perfusion	Same
Type of SpO2 Sensor	Transmittance Optical Sensor	Transmittance Optical Sensor	Same
Application Site	Fingertip	Fingertip	Same
Light Emitting	Red: 660 nm Infrared: 905nm	Red: 660 nm Infrared: 905nm	Same
SpO2 Measuring Range	0%-100%	0%-100%	Same
SpO2	1%	1%	Same

Features	**Subject Device** Fingertip Pulse Oximeter WIT-S200, WIT-S400	**Predicate Device K203854** Pulse Oximeter, Model: A2, A3, A4, A5	**Comparison**
Resolution			
SpO2 Accuracy	70~100%, ±2%. <70%, unspecified.	70~100%, ±2%. <70%, unspecified.	Same
PR Range	25 bmp – 250 bmp	30 bmp – 240 bmp	different
PR Accuracy	±3bpm	±1bpm	
PR Resolution	1 bpm	1 bpm	Same
Power source	2*AAA 1.5V alkaline battery	2*AAA 1.5V alkaline battery	Same
Type of Protection	Internal Powered	Internal Powered	Same
Degree of Protection – sensor	Type BF – applied part	Type BF – applied part	Same
Contacting material	ABS for enclosure, silicone for clip	ABS for enclosure, silicone for clip	Same
Contact type	Skin surface-contacting	Skin surface-contacting	Same
Patient Contact Materials	Complies with ISO10993-1	Complies with ISO10993-1	Same
Operating	Temperature: :10℃～40℃ Relative Humidity :30%～75% Atmospheric pressure: 700hPa~1060hPa	Temperature: 5℃ ～ 40℃ Humidity: 30% ～ 80% (non-condensing) Atmospheric pressure: 70kPa ～ 106kPa	different
Storage	Temperature :-40℃～+60℃ Relative humidity :5%～95% Atmospheric pressure: 500hPa~1060hPa	Temperature: -20℃ ～ +55℃ Humidity: 10% ～ 93% (non-condensing) Atmospheric pressure: 70kPa ～ 106kPa	different

In conclusion, the differences in technological characteristics do not raise new questions of safety and effectiveness.

8. Performance Data

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 FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Non-clinical data

The Pulse Oximeter has been tested according to the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+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 Edition 2.0 2015-01Medical 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
- ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.

The test was selected to show substantial equivalence between the subject device and the predicate.

Clinical data

Clinical studies were conducted to verify the accuracy of proposed device. The clinical studies were conducted per following standards:

- ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.
- Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff

Clinical hypoxia test results were obtained in human adult volunteers to validate the accuracy of Pulse Oximeter versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.