April 5, 2023

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: K213431
Trade/Device Name: Handheld Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA

Dear Kevin Wang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated **February 26th 2023**. Specifically, FDA is updating this SE Letter **due to an incorrect change made by the agency to the trade name** as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Vacant, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-7677, Ting.Song@fda.hhs.gov.

Sincerely,

Ting Song -S

For
Assistant 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

February 26, 2023

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: K213431
Trade/Device Name: Handheld Pulse Oximeter S0010B
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: January 26, 2023
Received: January 26, 2023

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)*
K213431

Device Name
Handheld Pulse Oximeter (model: WIT-100, WIT-300)

Indications for Use *(Describe)*
This Handheld Pulse Oximeter is intended for measuring and recording the functional oxygen saturation (SpO2) and pulse rate (PR). It is intended for spot check of SpO2, PR of adult patients in hospitals, clinics, or home. This 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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2023/01/26

1. Submission sponsor

Name: Shenzhen Witleaf Medical Electronics Co., Ltd.
Address: 13/F-B2, Block 1, Senyang Science Park, No.7 Road, West District of High-Tech Park, Guangming, Shenzhen City, Guangdong, 518109 P.R. China
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2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.
Address: Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong, P. R. China 518067
Contact person: Kevin Wang
E-mail: kevin@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Handheld Pulse Oximeter
Model	WIT-S100, WIT-S300
Common Name	Handheld Pulse Oximeter
Regulatory Class	Class II
Classification	21CFR 870.2700 / Oximeter / DQA
Submission type	Traditional 510(K)

4. Predicate Device

Manufacturer: Shenzhen Creative Industry Co., Ltd.
Device name: Pulse Oximeter, AP-10
510(K) Number: K201468

5. Device Description

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

The Handheld 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 Handheld Pulse Oximeter is powered by 3 AA batteries.

The device mainly composed of PCB board, On/Off button, mode button, OLED&LED screen, battery compartment, and plastic shell. The Handheld Pulse Oximeter is compatible with S0010B-S sensor. The device is a spot-check Handheld 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 Handheld Pulse Oximeter is intended for measuring and recording the functional oxygen saturation (SpO2) and pulse rate (PR). It is intended for spot check of SpO2, PR of adult patients in hospitals, clinics, or home. This device is not intended for continuous monitoring, use during motion or use with low perfusion.

7. Comparison to the Predicate Device

Features	**Subject Device** Handheld Pulse Oximeter, WIT-S100, WIT-S300	**Predicate Device** **K201468** Pulse Oximeter, AP-10	**Comparison**
Classification Regulation	21CRF 870.2700	21CRF 870.2700	Same
Classification and Code	Class II, DQA	Class II, DQA	Same
Common name	Handheld Pulse Oximeter	Pulse Oximeter	Same
Intended use	This Handheld Pulse Oximeter is intended for measuring and recording the functional oxygen saturation (SpO2) and pulse rate (PR). It is intended for spot check of SpO2, PR of adult patients in hospitals, clinics, or home. This device is not intended for continuous	This Pulse Oximeter is intended for measuring and recording the functional oxygen saturation (SpO2) and pulse rate (PR). It is intended for spot check and continuous recording of SpO2, PR of adult or pediatric patients in hospitals, clinics, or	Same

Features	**Subject Device** Handheld Pulse Oximeter, WIT-S100, WIT-S300	**Predicate Device** **K201468** Pulse Oximeter, AP-10	**Comparison**
	monitoring, use during motion or use with low perfusion.	home. This device is not intended for continuous monitoring.	
Patient populations	adult	adult or pediatric	Same
Type of SpO2 Sensor	Transmittance Optical Sensor	Transmittance Optical Sensor	Same
SpO2 Module	SpO2 Module with S0010B-S Probe	KM-SPO-04 SpO2 Module with KS-AR01 Probe	The difference of SpO2 Sensor does not raise any new questions of safety and effectiveness and still complies with the ISO80601-2-61
Application Site	Finger	Finger	Same
Light Emitting	Red: 660 nm Infrared: 905nm	Red: 660 nm Infrared: 905nm	Same
Display	2.8-inch OLED and LED	1.44” color TFT LCD	The display size difference does not raise any new questions of safety and effectiveness.
Measuring Mode	Spot-check and Continuous recording	Spot-check and Continuous recording	Same
SpO2 Measuring	0%-100%	0%-100%	Same

Features	**Subject Device** Handheld Pulse Oximeter, WIT-S100, WIT-S300	**Predicate Device** **K201468** Pulse Oximeter, AP-10	**Comparison**
Range			
SpO2 Resolution	1%	1%	Same
SpO2 Accuracy	70~100%, ±2%. <70%, unspecified.	70~100%, ±3%. <70%, unspecified;	The subject devices have better SpO2 accuracy, and it conforms with ISO 80601-2-61 as the predicate. The difference does not raise any safety and effectiveness questions.
PR Range	25 bmp – 250 bmp	30 bmp – 250 bmp	The subject devices have larger PR range, and it conforms with ISO 80601-2-61 as the predicate. The difference does not raise any safety and effectiveness questions.
PR Resolution	1 bpm	1 bpm	Same
PR Accuracy	±3bpm	±2bpm or ±2% (whichever is greater)	The subject devices have

Features	**Subject Device** Handheld Pulse Oximeter, WIT-S100, WIT-S300	**Predicate Device** **K201468** Pulse Oximeter, AP-10	**Comparison**
			larger PR accuracy, and it has been verified according to declared range and accuracy. The difference does not raise any safety and effectiveness questions.
Power source	3 AA batteries	Rechargeable Lithium-Ion Polymer Battery (3.7V,500mAh)	The subject devices use different power source which meets the design requirement and complies with the applicable standards, including IEC60601-1, IEC60601-1-2,etc
Type of Protection	Internal Powered	Internal Powered	Same
IP degree	IP22	IP22	Same
Degree of Protection – sensor	Type BF – applied part	Type BF – applied part	Same
Dimension (LxWxH)	143(L) × 80(W) × 30(H) mm	Watch Case: D 56mm× W 44mm×H	The physical dimension

Features	**Subject Device** Handheld Pulse Oximeter, WIT-S100, WIT-S300	**Predicate Device** **K201468** Pulse Oximeter, AP-10	**Comparison**
		16mm	difference does not raise any new questions of safety and effectiveness.
Weight	<0.5 kg (Excluding accessories)	Net Weight: about 45g	The weight difference does not raise any new questions of safety and effectiveness
Biocompatibility	Complies with ISO10993-1	Complies with ISO10993-1	Same
Patient Contacting material	Silicon for sensor ABS for Handheld unit TPU for Connecting wire	Silicon for sensor	Some material of the predicate device is not available. However, the materials used in proposed device is tested and passed the bio-compatibility test, so that the contacting material was proven to be safe to be

Features	Subject Device Handheld Pulse Oximeter, WIT-S100, WIT-S300	Predicate Device **K201468** Pulse Oximeter, AP-10	Comparison
			used.
Operating	Temperature: :0℃～40℃ Relative Humidity :15%～95% Atmospheric pressure: 70kPa~106kPa	Operating temperature: 5~40℃ Operating humidity: 15%~93% (non-condensing) Atmospheric pressure: 70kPa~106kPa	The operating condition difference does not raise any new questions of safety and effectiveness.
Storage	Temperature :-20℃～+60℃ Relative humidity :10%～95% Atmospheric pressure: 57.3kPa ～106.0kPa	Ambient temperature: -20ºC ~60ºC, Relative humidity 10%~95%, Atmospheric pressure: 50kPa~107.4kPa.	The storage condition difference does not raise any new questions of safety and effectiveness.

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 Handheld 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 Handheld 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 Handheld 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 Handheld Pulse Oximeter Equipment.
- Handheld Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff

Clinical hypoxia test results were obtained in 12 human adult volunteers to validate the accuracy of Handheld Pulse Oximeter versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

The pulse oximeter accuracy was tested in twelve healthy subjects, aged 21-50,with skin tones varying from Fitzpatrick I- VI.3 subjects had dark skin with Fitzpatrick V- VI.9 subjects had dark skin with Fitzpatrick I- IV. there were 6 males and 6 females taking part in this testing. The 12 subjects are health adult, and come from Africa(3), Caucasian(5)&Asian(4) which include Medium, light &dark race.

9. Conclusion

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