510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

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1. Submission sponsor

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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.