February 25, 2022

Shenzhen Mericonn Technology 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: K212300
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: February 25, 2022
Received: February 23, 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 and Part 809); 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 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)*
K212300

Device Name
Pulse Oximeter (Model: PO101, PO102, PO103)

Indications for Use *(Describe)*
This 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 or pediatric patients (weight >=40kg) in hospitals, clinics, or home. This device is not intended for continuous monitoring. It is intended to be used by both lay person or healthcare professional in the home environment.

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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5

510(k) Summary

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2022/2/7

1. Submission sponsor

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2. Submission correspondent

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Contact person: Kevin Wang
E-mail: kevin@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Pulse Oximeter
Model	PO101, PO102, PO103
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 Creative Industry Co., Ltd.
Device name: Pulse Oximeter, AP-10
510(K) Number: K201468

5. Device Description

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

The 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 Pulse Oximeter is powered by 2 AAA alkaline batteries.

The device mainly composed of PCB board, On/Off button, mode button, OLED&LED screen, battery compartment, and plastic shell. The device is a spot-check 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 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 or pediatric patients (weight >=40kg) in hospitals, clinics, or home. This device is not intended for continuous monitoring. It is intended to be used by both lay person or healthcare professional in the home environment.

7. Comparison to the Predicate Device

Features	**Subject Device** Pulse Oximeter, PO101/PO102/PO103	**Predicate Device** **K201468** Pulse Oximeter, AP-10	**Comparison**
Applicant	Shenzhen Mericonn Technology Co., Ltd.	Shenzhen Creative Industry Co., Ltd.	/
Classification Regulation	21CRF 870.2700	21CRF 870.2700	Same
Classification and Code	Class II, DQA	Class II, DQA	Same
Common name	Pulse Oximeter	Pulse Oximeter	Same
Intended use	This 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 or pediatric	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	The subject devices do not support continuous recording compared with the predicate, but the rest is the same. The difference does not raise any safety and effectiveness questions.

Features	**Subject Device** Pulse Oximeter, PO101/PO102/PO103	**Predicate Device** **K201468** Pulse Oximeter, AP-10	**Comparison**
	patients in hospitals, clinics, or home. This device is not intended for continuous monitoring. It is intended to be used by both lay person or healthcare professional in the home environment.	hospitals, clinics, or home. This device is not intended for continuous monitoring.	
Patient populations	adult or pediatric	adult or pediatric	Same
Type of SpO2 Sensor	Transmittance Optical Sensor	Transmittance Optical Sensor	Same
Application Site	Finger	Finger	Same
Light Emitting	Red: 660 nm Infrared: 905nm	Red: 660 nm Infrared: 905nm	Same
Measuring Mode	Spot-check	Spot-check and Continuous recording	Different
SpO2 Measuring Range	35%-100%	0%-100%	Different
SpO2 Resolution	1%	1%	Same
SpO2 Accuracy	70~100%, ARMS±3%. <70%, unspecified.	70~100%, ±3%. <70%, unspecified;	Same
PR Range	30 bmp – 250 bmp	30 bmp – 250 bmp	Same
PR Resolution	1 bpm	1 bpm	Same
PR Accuracy	±2bpm or±2% select larger	±2bpm or ±2% (whichever is greater)	Same
Power source	2 AAA alkaline batteries	Rechargeable Lithium-Ion Polymer Battery (3.7V,500mAh)	Different
Data update	/	USB, Bluetooth	Different

Features	Subject Device Pulse Oximeter, PO101/PO102/PO103	Predicate Device **K201468** Pulse Oximeter, AP-10	Comparison
Type of Protection	Internal Powered	Internal Powered	Same

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.

Software

Software verification and validation were provided in compliance with FDA Guidance for the Content of the Premarket Submission for Software Contained in Medical Devices. These verifications and validations demonstrate that the subject device work functionally and the software for the device is considered as a "moderate" level of concern, as defined by the FDA guidance.

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

The subject devices are considered surface contacting for a duration of not exceed 24 hours.

Non-clinical data

The Pulse Oximeter has been tested according to 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 60601-1-2:2014, 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.