January 4, 2024

Cofoe Medical Technology Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801,No.161,East Lujiazui Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K230277
Trade/Device Name: Pulse Oximeter(Model OHT60,OXH78)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 30, 2023
Received: December 4, 2023

Dear Boyle 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
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)*
K230277

Device Name
Pulse Oximeter (Model OHT60,OXH78)

Indications for Use *(Describe)*
The Pulse Oximeter is intended for spot-checking oxygen saturation and pulse rate, and the device is a reusable device and intended to be used with the finger of adults in professional healthcare facility or home conditions when physician follow-up and operated by a physician. And it is not intended to be used under motion.

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

K230277

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

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Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Email: Info@truthful.com.cn

Date of Preparation: Dec.25,2023

2.0 Device Information

Trade name: Pulse Oximeter
Common name: Pulse Oximeter
Classification name: Oximeter
Model(s): Model OHT60, Model OXH78
Production code: DQA
Regulation number: 21 CFR 870.2700
Classification: Class II
Panel: Anesthesiology

3.0 Predicate Device Information

Manufacturer: Huizhou Xiaoou Technology Co., Ltd.
Trade name: Pulse Oximeter (Model Number-SO611), Pulse Oximeter (Model Number-SO711), Pulse Oximeter (SO811), Pulse Oximeter

(SO911)
510(k) number: K212665

4.0 Indication for Use Statement

The Pulse Oximeter is intended for spot-checking oxygen saturation and pulse rate, and the device is a reusable device and intended to be used with the finger of adults in professional healthcare facility or home conditions when physician follow-up and operated by a physician. And it is not intended to be used under motion.

5.0 Device Description

The pulse oximeter, Model OHT60 and OXH78, consists of probe, electronic circuits, and display and plastic enclosures, is designed for spot checking of the pulse oxygen saturation and pulse rate for adults in a professional healthcare facility or home conditions when physician follow-up and operated by a physician. This medical device can be reused. Not for continuously monitoring.

SpO2 is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO2 measuring unit. The measurement principle of Pulse oximeter is based on the absorption spectrum characteristics of hemoglobin and oxyhemoglobin in red and infrared regions, and the empirical formula of data is established by using ' Lambert Beer ' law. The working principle of the instrument adopts photoelectric blood oxygen detection technology combined with volume pulse recording technology, The specific process is as follows: Firstly, the infrared light emitting at 660 nm and the near-infrared light emitting at 905 are used to irradiate the finger and the measurement data are obtained by the infrared receiver tube. Secondly, the obtained measurement data were calculated and processed by electronic circuits and microprocessors to obtain the blood oxygen saturation and pulse rate, and the calculation results were displayed on the screen.

The subject device is a reusable device, and need to reprocess as suggested in the user manual after each use. And the device is intended to be used on the finger, and powered by 2*1.5V AAA alkaline batteries.

The Model OHT60 and OXH78 have the same critical components and its materials and means of power supply, PCB layout and Software are little different.

6.0 Technological Characteristics

Principle of Operation
The module utilizes the same principles of operation for pulse oximetry governed by the following principles:
1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood)

differ in their absorption of red and infrared light (spectrophotometry).
2. The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Mechanism of Action for Achieving the Intended Effect

A mathematic 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: Photoeletric Oxyhemoglobin Inspection Technology adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 905nm near infrared light) can be focused on a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeters display through process in electronic circuits and microprocessor.

7.0 Non-clinical Testing Summary

The following performance data have been conducted to verify that the Oximeter meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

Conclusions for Biocompatibility Testing
The biocompatibility evaluation for the oximeter was conducted in accordance with the FDA's Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process'" ， as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of permanent (>30 days).
And the testing included the following tests:
➢ Cytotoxicity, per ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
➢ Skin Sensitization and Skin Irritation, per ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

According to the Attachment G: Biocompatibility of Certain Devices in
Contact with Intact Skin of FDA Guidance Use of International Standard ISO10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", issued on: September 8, 2023. Acrylonitrile butadiene styrene (ABS), Polycarbonate (PC) and Silicone materials are considered to pose a very low biocompatibility risk because they have a long history of safe use in medical devices that contact intact skin.
So the specific biocompatibility testing for Case, Keys and Silicone are not necessary.

Electrical and EMC Safety:

The electrical safety and EMC safety testing was performed to, and passed, the following standards:

➢ IEC 60601-1:2005/AMD2:2020, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

➢ 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

➢ 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

Summary of Bench Testing

Bench testing was conducted and the results show that the subject device complies with the below standard:

➢ 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

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for software with a moderate level of concern.

The Software Validation is in compliance with FDA Guidance.

Summary of Shelf Life and Cleaning Testing

The service life has been verified through accelerated aging. The service life is 5 years except the battery is reasonable and effective.

Cleaning and disinfection validation testing was conducted in accordance with FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” issued March 17,2015. Moreover, the performance of the subject device shows no degradation after repeated cleaning and disinfection as suggested in the User manual.

8.0 Clinical Test Summary

Clinical studies were conducted at Sir Run Run Shaw Hospital, School of Medicine, Zhejiang University to verify the accuracy of the subject device.

The clinical study was conducted in accordance to ISO80601-2-61:2017, ISO14155:2020, and the FDA Guidance Document for Pulse Oximeters. The subject device of this study was to verify the accuracy of pulse oximetry (SpO2) measured by the oximeter with a measurement range of 70-100% in the static state.

The induced Fraction of inspiration O2 (FiO2) control test was performed on subjects, and the subjects were subjected to radial artery puncture and indwelling catheter to obtain a stable arterial blood sample. The pulse oxygen saturation (SpO2) measured by the oximeter is compared with the functional oxygen saturation (SaO2) in arterial blood is analyzed by the arterial blood gas analyzer(CO-OXIMETER).

12 healthy adult volunteer subjects (ages 21-42yr, 46-75kg, 150-180cm, with light to dark pigmentation) were included in the study conducted to evaluate and complete the SpO2 accuracy performance of the Pulse Oximeter. 4 males and 8 females (including 4 subjects with Fitzpatrick V, VI, 8 subjects with Fitzpatrick I ~ Fitzpatrick IV).

Subject No	Site	Enrollment Date	Treatment Received	Adherence to Protocol	Adverse Events
1~12	Sir Run Run Shaw Hospital, 01 School of Medicine, Zhejiang University	2021.07.26	OHT60 Pulse Oximeter	Yes	No

The measure result between the SpO2 measured by subject device and the SaO2 measured by the blood gas analyzer.

The SpO2 accuracy performance results showed the subject Pulse Oximeter to have an ARMS of 1.98 during steady state conditions over the range of 70-100%.

9.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K230277	Predicate Device K212665	Remark
Product Name	Pulse Oximeter	Pulse Oximeter	--
Manufacturer	Cofoe Medical Technology Co., Ltd.	Huizhou Xiaoou Technology Co., Ltd.	--
Product Code	DQA	DQA	Same
Regulation No.	21CFR 870.2700	21CFR 870.2700	Same
Class	Class II	Class II	Same
Model	OHT60,OXH78	SO611,SO711,SO811,SO911	--
Intended Use/Indication for Use	The Pulse Oximeter is intended for spot-checking oxygen saturation and pulse rate, and the device is a reusable device and intended to be used with the finger of adults in professional healthcare facility or home conditions when physician follow-up and operated by a physician. And it is not intended to be used under motion.	The Pulse Oximeter is intended for spot-checking oxygen saturation and pulse rate, and the device is a reusable device and intended to be used with the finger of adults in professional healthcare facility or home conditions when physician follow-up and operated by a physician. And it is not intended to be used under motion or low perfusion scenarios.	Same
Principle	The oximeter consists of probe, electronic circuits, and display and plastic enclosures. And one side of probe is designed to locate light emitting diodes and a light detector (called a photo-detector). Red and Infrared lights are shone through the tissues from one side of the probe to the other. Then parts of the light emitted absorbed by blood and tissues. The light absorbed by the blood varies with the oxygen saturation of haemoglobin. After that, the photo-detector detects the light volume transmitted through the tissues which depends on blood pulse, Hereafter, the microprocessor calculates a value for the oxygen saturation (SpO_2).	The oximeter consists of probe, electronic circuits, and display and plastic enclosures. And one side of probe is designed to locate light emitting diodes and a light detector (called a photo-detector). Red and Infrared lights are shone through the tissues from one side of the probe to the other. Then parts of the light emitted absorbed by blood and tissues. The light absorbed by the blood varies with the oxygen saturation of haemoglobin. After that, the photo-detector detects the light volume transmitted through the tissues which depends on blood pulse, Hereafter, the microprocessor calculates a value for the oxygen saturation (SpO_2).	Same
Applied Population	Adults in home & hospital	Adults in home & hospital	Same
Application sites	Finger	Finger	Same
Display Type	LED	LED	Same
Display Content	OHT60: Display the SPO2, PR, pulse intensity histogram, Oxygen saturation value of pulse and battery power status. OXH78: Display the SPO2, PR, pulse intensity histogram, perfusion index, pulse waveforms and battery power status	Display the SpO2%, PR, battery indicator, Pulse rate bar graph，pulse waveform	Similar
Contacting material	Shell: ABS Clip pad: Silicon Key:PC	Not Publicly available	Different

Analysis:

Materials of the predicate device is not publicly available. The biocompatibility evaluation has performed and passed on the subject device and the predicate device per the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

Table 2 Performance Comparison

Item	Subject Device K230277	Predicate Device K212665	Remark
Model	OHT60, OXH78	SO611,SO711,SO811,SO911	/
LED wavelength	Red= 660 nm; Infrared=905nm	Red= 660 nm; Infrared=905nm	Same
Power source	2*1.5V AAA alkaline battery	2*1.5V AAA alkaline battery	Same
Display	OHT60: SpO2%; PR; battery level; Pulse intensity histogram. OXH78: SpO2%; PR; battery level; Pulse intensity histogram, Pulse wave form	SpO2%; PR	Same
SpO2 Measuring Range	35%-100%	0%-100%	Different
SpO2 Resolution	1%	1%	Same
SpO2 Accuracy	70~100%, ±3%; 0% to 69%: unspecified	70~100%, ±2%; 0% to 69%: unspecified	Similar
PR Measuring Range	30-250BPM	30-250BPM	Same
PR Resolution	1 bpm	1 bpm	Same
PR Accuracy	± 3bpm	±3 bpm	Same

Analysis:

The SpO_2 measurement range and accuracy is a little different, but they are within the limits of the specified range of the standard ISO 80601-2-61 and FDA guidance for Pulse Oximeters. The different has no effect on substantive equivalence.

Table 3 Safety Comparison

Item	Subject Device K230277	Predicate Device K212665	Remark
Electrical Safety	Comply with IEC 60601-1 IEC 60601-1-11	Comply with IEC 60601-1 IEC 60601-1-11	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Performance	ISO 80601-2-61	ISO 80601-2-61	Same
Biocompatibility	Comply with ISO 10993-1, FDA Guidance	Comply with ISO 10993-1, FDA Guidance	Same

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device.