March 8, 2023

Beijing Choice Electronic Technology Co., Ltd.
Haiying Zhao
Quality Director
2nd Floor 3rd Floor and Room 410-412 4th Floor
No. 2 Building No. 9 Shuangyuan Road Shijingshan
Beijing, Beijing 100041
China

Re: K220101
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: February 21, 2023
Received: March 2, 2023

Dear Haiying Zhao:

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)*
K220101

Device Name
Pulse Oximeter

Indications for Use *(Describe)*
The Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent, child and infant patients in hospitals, hospital-type facilities and homecare. The device is not intended to be used under motion and low perfusion. It is designed for finger thickness between 0.8cm and 2.2cm (0.3 inches to 0.9 inches).

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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# Section II 510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

There is no prior submission for the device.

## 1. Submitter Information

**Manufacturer**

Establishment Registration Number: 3005569927

Beijing Choice Electronic Technology Co., Ltd.

2nd Floor, 3rd Floor and Room 410-412 4th Floor, No. 2 Building, No. 9 Shuangyuan Road, Shijingshan District BEIJING, 100041, P.R. China.

**Contact Person**

Haiying Zhao

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Date prepared: November 10, 2021

## 2. Identification of Proposed Device

Device Common Name: Oximeter

Device Trade/Proprietary Name: Pulse Oximeter

Model: MD300CN130, MD300CN356

Classification Name: Oximeter

Regulation Number: 870.2700

Product Code: DQA

Regulatory Class: Class II

Panel: Anesthesiology

## 3. Device Description

The proposed device, Pulse Oximeter, is a battery powered device, which can mainly detect and display the measured oxyhemoglobin saturation (SpO2) and pulse rate (PR) value. It available two models, MD300CN130 and MD300CN356. The model MD300CN130 is adopted LED screen to display SpO2 and Pulse Rate (PR) value, low power indication and pulse bar, the device has 2 display modes. The model MD300CN356 using LCD screen with 7 display modes, it can display SpO2, Pulse Rate (PR), Perfusion Index (PI), waveform, battery indicator, signal indicator and pulse bar, the brightness level can be adjusted

1-10 level.

The proposed device consists of power supply module, detector and emitter LED, signal collection and process module, display module, user interface and button control circuit.

The enclosure of the proposed device is made of ABS and the fingertip cushion is made of Silicone Gel.

The proposed device is not for life-supporting or life-sustaining, not for implant.

The device is not sterile, and the transducers are reusable and do not need sterilization and re-sterilization.

The device is for prescription.

The device does not contain drug or biological products.

**4. Identification of Predicate Device**

Trade/Proprietary Name: Fingertip Pulse Oximeter

Model: MD300CI218

Common Name: Pulse Oximeter

K-number: K181503

Regulation Number: 21 CFR 870.2700

Device Class: II

Product Code: DQA

Panel: Anesthesiology

Manufactured by: Beijing Choice Electronic Technology Co., Ltd.

## 5. Substantially Equivalent (SE) Comparison

Table 1 Comparison Table between the Proposed Device and Predicate Device

| **Comparison Elements** | **Proposed Device** | | **Predicate Device (K181503)** | **Remark** |
|---|---|---|---|---|
| | **MD300CN130** | **MD300CN356** | | |
| Product Name | Pulse Oximeter | | Fingertip Pulse Oximeter | / |
| Model | MD300CN130 | MD300CN356 | MD300CI218 | / |
| Regulation No. | 21 CFR 870.2700 | | 21 CFR 870.2700 | Same |
| Regulatory Class | II | | II | Same |
| Classification Name | Oximeter | | Oximeter | Same |
| Product Code | DQA | | DQA | Same |
| Intended Use | The Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent, child and infant patients in hospitals, hospital-type facilities and homecare. The device is not intended to be used under motion and low perfusion. It is designed for finger thickness between 0.8cm and 2.2cm (0.3 inches to 0.9 inches). | | The Fingertip Pulse Oximeter MD300CI218 is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent, child and infant patients in hospitals, hospital-type facilities and homecare environment. | Similar 1 |
| Intended Population | Adult, adolescent, child and infant patients | | Adult, adolescent, child and infant patients | Same |
| Components | Power supply module, detector and emitter LED, signal collection and processor module, display module, user interface and button control. | | Power supply module, detector and emitter LED, signal collection and processor module, display module, Bluetooth module, user interface and button control. | Similar, Analysis 2 |
| Design Principle | The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains | | The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular | Same |

| Comparison Elements | | Proposed Device | | Predicate Device (K181503) | Remark |
|---|---|---|---|---|---|
| | | MD300CN130 | MD300CN356 | | |
| | | a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector 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. | | bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector 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. | |
| Measurement Wavelength | Red | 660± 3nm | | 660± 3nm | |
| | Infrared | 905± 10nm | | 905± 10nm | |
| Design Features | Display Type | LED | LCD | OLED | Different□ Analysis 3 |
| | Working Time | continuously operated as long as 18 hours | continuously operated as long as 20 hours | continuously operated as long as 18 hours | Similar□ Analysis 4 |
| | Display Mode | 2 display modes | 7 display modes | 2 display modes | Similar, Analysis 5 |
| Power supply | | 2*AAA alkaline batteries | | 2*AAA alkaline batteries | Same |
| Performance Data | | SpO2, PR | SpO2, PR, PI | SpO2, PR | Similar, Analysis 6 |

| **Comparison Elements** | | **Proposed Device** | | **Predicate Device (K181503)** | **Remark** |
|---|---|---|---|---|---|
| | | **MD300CN130** | **MD300CN356** | | |
| SpO2 | SpO2 Display Range | 0%~100% | | 0%~100% | |
| | SpO2 Measurement Range | 70%~100% | | 70%~100% | |
| | SpO2 Accuracy | 70%~100%, ± 2%;<br>0~69% no definition | | 70%~100%, ± 2%;<br>0~69% no definition | |
| | SpO2 Resolution | 1% | | **1%** | |
| PR | PR Display Range | 30 bpm~250 bpm | | 30 bpm~250 bpm | |
| | PR Measurement Range | 30 bpm~250 bpm | | 30 bpm~250 bpm | |
| | PR Accuracy | 30 bpm~99 bpm, ± 2 bpm;<br>100 bpm~250 bpm, ± 2% | | 30 bpm~99 bpm, ± 2 bpm;<br>100 bpm~250 bpm, ± 2% | |
| | PR Resolution | 1 bpm | | 1 bpm | |
| PI | Display range | NA | 0.1%~20% | NA | |
| | Measure range | NA | 0.3~20.0% | NA | |
| | Resolution | NA | 0.1% | NA | |
| Transmitter | | NA | | Bluetooth Compliance: Version 4.0 | Similar, Analysis 7 |
| Environment | Operating Temperature | 0℃ ~ 40℃ | | 5℃ ~ 40℃ | Similar, Analysis 8 |
| | Storage/Transport temperature | -25℃ ~ 70℃ | | -25℃ ~ 70℃ | |
| | Relative Humidity | 15%~93% no condensation in operation;<br>≤93% no condensation in storage/transport | | 15%~93% no condensation in operation;<br>≤93% no condensation in storage/transport | |
| | Atmosphere Pressure | 70kPa~106kpa | | 70kPa~106kpa | |

| **Comparison Elements** | | **Proposed Device** | | **Predicate Device (K181503)** | **Remark** |
|---|---|---|---|---|---|
| | | **MD300CN130** | **MD300CN356** | | |
| Contacting Material | Battery Cover | ABS | | ABS | Different 9 |
| | Enclosure | ABS | | ABS | |
| | Screen protect film | PMMA | | PMMA | |
| | Power Button | Silica gel | | ABS | |
| | Fingertip Cushion | Silica gel | | Silica gel | |
| Testing | Laboratory Testing | The laboratory tests include SpO2□ PR and PI (only apply for MED300CN356) accuracy Test, Weak Perfusion Test, High and Low Temperature and Humidity Test, Performance Test After Cleaning and ISO 80601-2-61 | | The laboratory tests include SpO2 and PR accuracy Test, Weak Perfusion Test, High and Low Temperature and Humidity Test, Performance Test After Cleaning and ISO 80601-2-61 | Similar, Analysis 10 |
| | Electrical Safety | Conformed to IEC60601-1, IEC 60601-1-11 | | Conformed to IEC60601-1, IEC 60601-1-11 | |
| | Electromagnetic Compatibility | Conformed to IEC60601-1-2 | | Conformed to IEC60601-1-2 | |
| | Software | Compliance with FDA Guidance for the content of Premarket Submissions for Software Contained in Medical Devices | | Compliance with FDA Guidance for the content of Premarket Submissions for Software Contained in Medical Devices | |

| **Comparison Elements** | **Proposed Device** | | **Predicate Device (K181503)** | **Remark** |
|---|---|---|---|---|
| | **MD300CN130** | **MD300CN356** | | |
| Label and Labeling | Compliance with the Guidance of pulse oximeter-premarket notification issued on March 4,2013 | | Compliance with the Guidance of pulse oximeter-premarket notification issued on March 4,2013 | Same |

Analysis 1 – Intended Use

The intended use of proposed device is similar with the predicate device. The intended function and population of proposed device and predicate device is the same. The intended use of proposed device provided more detailed description of the usage scenarios, in order to give better understand for home use. This difference does not affect the substantially equivalence between proposed device and predicate device on safety and effectiveness.

The intended use

Analysis 2 – Components

The components of proposed device are similar with predicate device but it does not have the Bluetooth module. The Bluetooth module is the independent module that does not affect other function of device. In addition, the final products of proposed device have been verification and validation and the results could meet the requirement of *IEC 60601-1, IEC 60601-1-11, IEC60601-1-2* and *ISO 80601-2-61*, *Submissions for Software Contained in Medical Devices*. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 3 - Display Type

The proposed device has the different display type with the predicate device. The mode MD300CN130 of proposed device is configurated with the LED display, the mode MD300CN356 are configurated with the LCD display while the predicate device is using the OLED display. The varies display type is due to different marked strategy. In addition, the final products have been verification and validation and the result could meet the requirement of *IEC 60601-1, IEC 60601-1-11, IEC60601-1-2* and *ISO 80601-2-61.* Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 4 - Working Time

The working time of proposed device is different from predicate device. This is depended on different hardware and software design of each model. However, the final products have been verification and validation and the result could meet the requirement of *IEC 60601-1, IEC 60601-1-11, IEC60601-1-2* and *ISO 80601-2-*

*61*. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 5 - Display Mode

The display mode of the proposed device is different from the predicate device. The varies display modes provides more choices for consumer. The display mode is depended on the display type and embedded software. However, the final products have been verification and validation and the result could meet the requirement of *ISO 80601-2-61*. In addition, the embedded software could meet the requirements of *Submissions for Software Contained in Medical Devices*. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 6 - Performance Data

The mode MD300CN130 of proposed device can measure the SpO2 and PR value, that is same with the predicate device. Meanwhile, the mode MD300CN356 has on more PI performance data compare with the predicate device. In addition, the parameters of SpO2 and PR for proposed device are totally same with the predicate device. The PI function had been verification through the bench test per *ISO 80601-2-61* and the result could meet the requirement. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 7 - Transmitter

The proposed device does not have the Bluetooth function which is different from predicate device. The Bluetooth is the independent function module, it will not affect other functions. In addition, the embedded software could meet the requirements of *Submissions for Software Contained in Medical Devices*. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 8 - Environment

The Operating Temperature of proposed device is different with the predicate device and other environment requirements are same. The lower limit operating temperature of proposed device is 0℃ which the predicate device is 5℃. However, the operating temperature of proposed device has been verification according to standard *ISO 80601-2-61*. All the results can meet the standard requirements. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Different 9 - Contacting Material

The contact materials of proposed device are different with the predicate device. All of the contact materials of the proposed device have been done the biocompatibility test per ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process and the results

can meet the standard requirements. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 10 – Testing

The mode MD300CN356 have one more PI function compare with the predicate device. The PI function had been verified through the bench test per *ISO 80601-2-61*. The test result can meet the requirement of the standard. Therefore, this difference does not affect the substantially equivalence between the proposed device and predicate device on safety and effectiveness.

## 6. Intended Use

The Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent, child and infant patients in hospitals, hospital-type facilities and homecare. The device is not intended to be used under motion and low perfusion. It is designed for fingers between 0.8cm and 2.2cm (0.3 inches to 0.9 inches).

## 7. Test Summary

**Non-Clinical Test Conclusion**

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards and guidance:

- IEC60601-1: 2005, AMD1:2012, AMD2:2020 Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance
- IEC60601-1-11: 2015, AMD1:2020 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.
- IEC60601-1-2: 2020 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- ISO 80601-2-61:2017 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
- The Software Validation is in compliance with FDA Guidance to Compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- ISO10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

**Clinical Test**

A clinical study was conducted per the requirement of Annex EE of ISO 80601-2-61 to validate the SpO2 accuracy of proposed pulse oximeter. The purpose of the clinical study was to evaluate the SpO2 accuracy performance of the pulse oximeter during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to arterial blood co-oximeter. 11 healthy adult volunteer subjects (ages 20-42yr, with light to dark pigmentation, include male and female) were included in the study conducted to evaluate the SpO2 accuracy performance of proposed three models. Each system was evaluated during steady state/non-motion conditions with various levels of induced hypoxia resulting in stable oxygen saturation levels between 100% and 70% SaO2. Arterial blood samples were drawn during simultaneous data collection from the test devices. The blood was immediately analyzed on reference co-oximeter providing functional SaO2 for the basis of the SpO2 accuracy comparison. The results of the testing demonstrate that all requirements and performance specifications were satisfied and the subject device is substantially equivalent to its predicates.

## 8. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device.