June 21, 2024

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
Beijing, Shijingshan 100041
China

Re: K232975
Trade/Device Name: Pulse Oximeter (MD300C228)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: May 17, 2024
Received: May 17, 2024

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 (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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232975

Device Name

Pulse Oximeter (MD300C228)

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 can be used by the people whose finger thickness is between 8mm and 22mm(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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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 Name:**

Establishment Registration Number: 3005569927

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- **Contact Person:**

Haiying Zhao

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- **Date prepared：** September 15, 2023

2. Subject Device Information

Device Trade/Proprietary Name: Pulse Oximeter

Regulation Medical Specialty: Cardiovascular

Device Classification Name: Oximeter

Model: MD300C228

Purpose of submission: 510(k)

Regulation Number: 21 CFR 870.2700

Product Code: DQA

Class: Ⅱ

Panel: Anesthesiology

3. Predicate Device

510(k) Number: K181503

Device Trade/Proprietary Name: Pulse Oximeter

Regulation Medical Specialty: Cardiovascular

Device Classification Name: Oximeter

Model: MD300CI218

Product Code: DQA

Regulation Number: 21 CFR 870.2700

Device Class: Ⅱ

Panel: Anesthesiology

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.

4. 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. The MD300C228 is adopted LCD screen to display to display SpO2, Pulse Rate value (PR), Perfusion Index (PI), pulse bar, brightness level, battery indicator, signal indicator and waveform, it has 7 display modes, the brightness level can be adjusted 1-5 level. The measured data can be transmitted to APP through Bluetooth. The device is normally applied to adult, adolescent child and infant patients in hospitals, hospital-type facilities and homecare.

The subject device is composed of following components to achieve the above detection process: power

supply module, detector and emitter LED, signal collection and process module (MCU), LCD display screen, user interface and button control circuit.

Principle of the oximeter is as follows: The pulse oximeter works by applying a sensor to a fingertip. 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 SpO_2.

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

The subject 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.

5. Comparison list of the technological characteristics

Table 1 Performance Specification Comparison Table between the Subject Device and Predicate Device

Comparison Elements	**Proposed Device**	**Predicate Device (K181503)**	**Remark**
Product Name	Pulse Oximeter	Fingertip Pulse Oximeter	/
Model	MD300C228	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 can be used by the people whose finger thickness is between 8mm and 22mm(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.	Same
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, Bluetooth 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.	Same
Design Principle	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	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	Same

Comparison Elements		**Proposed Device**	**Predicate Device (K181503)**	**Remark**
		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.	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	LCD	OLED	Different，Analysis 1
	Working Time	continuously operated as long as 20 hours	continuously operated as long as 18 hours	Similar, Analysis 2
	Display Mode	7 display modes	2 display modes	Different, Analysis 3
Power supply		2*AAA alkaline batteries	2*AAA alkaline batteries	Same
Performance Data		SpO2, PR, PI	SpO2, PR	Similar, Analysis 4
SpO2	SpO2 Display Range	0%~100%	0%~100%	
	SpO2 Measurement Range	70%~100%	70%~100%	
	SpO2 Accuracy	70%~100%, ± 2%; 0~69% no definition	70%~100%, ± 2%; 0~69% no definition	
	SpO2 Resolution	**1%**	**1%**	

Comparison Elements		**Proposed Device**	**Predicate Device (K181503)**	**Remark**
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; 100 bpm~250 bpm, ± 2%	30 bpm~99 bpm, ± 2 bpm; 100 bpm~250 bpm, ± 2%	
	PR Resolution	1 bpm	1 bpm	
PI	Display range	0.1%~20%	NA	
	Measure range	0.3~20.0%	NA	
	Resolution	0.1%	NA	
Transmitter		Bluetooth Compliance: Version 5.0	Bluetooth Compliance: Version 4.0	Similar, Analysis 5
Environment	Operating Temperature	0℃ ~ 40℃	5℃ ~ 40℃	Similar, Analysis 6
	Storage/Transport temperature	-25℃ ~ 70℃	-25℃ ~ 70℃	
	Relative Humidity	15%~93% no condensation in operation; ≤93% no condensation in storage/transport	15%~93% no condensation in operation; ≤93% no condensation in storage/transport	
	Atmosphere Pressure	70kPa~106kpa	70kPa~106kpa	
Contacting Material	Battery Cover	ABS	ABS	Same
	Enclosure	ABS	ABS	
	Screen protect film	PMMA	PMMA	
	Power Button	ABS	ABS	

Comparison Elements		**Proposed Device**	**Predicate Device (K181503)**	**Remark**
	Fingertip Cushion	Silica gel	Silica gel	
Testing	Laboratory Testing	The laboratory tests include SpO2， PR and PI 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	Same
	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	
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 - Display Type

The proposed device has the different display type with the predicate device. The proposed device is 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. The test result is provided in Bench Testing section of this submission. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 2 - 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. The test result is provided in Bench Testing section of this submission. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 3- 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. The test result is provided in Bench Testing section of this submission. In addition, the embedded software could meet the requirements of Submissions for Software Contained in Medical Devices, the related document of software could refer to Software Documentation section of this submission. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 4 - Performance Data

The proposed device can measure and display the SpO2, PR and PI value, while the predicate device cannot display PI value. 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. The test result is provided in Bench Testing section of this submission. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 5 - Transmitter

The proposed device is configured the Bluetooth 5.0 module which predicate device is configured the Bluetooth 4.0 module. The Bluetooth is the independent function module, it would not affect other function module of the device. In addition, the embedded software could meet the requirements of Submissions for Software Contained in Medical Devices, the related document of software could refer to Software Document section of this submission. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.

Analysis 6 - 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. The test result is provided in Bench Test section of this submission. 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

6. Indications for use

The Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate of adult, adolescent child and infant patients in hospitals, hospital-type facilities and homecare. The device can be used by the people whose finger thickness is between 8mm and 22mm(0.3 inches to 0.9 inches).

7. Testing

The Pulse Oximeter MD300C228 was supported by both laboratory and clinical accuracy testing in order to ensure that they were appropriate performance and functional features to fully comply with recognized standards and is substantially equivalent to the predicate device.

Non-clinical Test

The Pulse Oximeter MD300C228 is designed and tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- 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.
- IEC60601-1-2:2014, AMD1:2020 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- ISO80601-2-61:2017 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

We have performance tests per FDA guidance "Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers".

The Software Validation is in compliance with FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Compliant to FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

Table 2 The list of non-clinical test performed on the subject devices.

No.	Test Name
1	System Performance Test
2	Performance Test according to ISO 80601-2-61: 2017
3	Electromagnetic Compatibility Test According to IEC60601-1-2:2014, AMD1:2020
4	Electrical Safety Test According to IEC60601-1: 2005, AMD1:2012, AMD2:2020
5	Used in the home healthcare environment test according to IEC60601-1-11: 2015, AMD1:2020
6	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ISO 10993-1:2018
7	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO10993-5:2009
8	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization ISO 10993-10:2021

The test results indicate that the safety and effectiveness of the subject device is substantially equivalent to that of the predicate device.

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 device. The device 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 SpO2 accuracy performance results showed the pulse oximeter to have an Arms of 1.8 during steady state conditions over the range of 70-100%. 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. Determination of substantial equivalence

The subject device of Pulse Oximeter MD300C228 has the same classification information, same intended use, similar components, same performance effectiveness as the predicated device. The subject device is Substantially Equivalent (SE) to the predicate device which is US legally market device.