August 12, 2023

Beijing Choice Electronic Technology Co., Ltd.
Haiying Zhao
Quality Director
No. 9 Shuangyuan road, Badachu Hi-tech Zone
Shijingshan District
Beijing, Beijing 100041
China

Re: K230172
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 12, 2023
Received: July 12, 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,

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)*
K230172

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 for continuous monitoring, use during motion or use with low perfusion. The device is intended for reuse. The device is wearing on fingertips while using.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

2.1 Submitter Information

- **Manufacturer Name:**

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 100041 Beijing PEOPLE'S REPUBLIC OF CHINA

- **Contact Person:**

Haiying Zhao

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 100041 Beijing PEOPLE'S REPUBLIC OF CHINA

Phone: +86-10-88204631

Fax: +86-10-88204632

Email: cc@choicemmed.com

- **Date prepared**： February 10,2023

2.2 Subject Device Information

Device Trade/Proprietary Name: Pulse Oximeter

Regulation Medical Specialty: Cardiovascular

Device Classification Name: Oximeter

Model: MD300C19

Purpose of submission：510（k）

Regulation Number: 21 CFR 870.2700

Product Code: DQA

Class: Ⅱ

Panel: Anesthesiology

2.3 Predicate Device

510(k) Number: K181503

Device Trade/Proprietary Name: Fingertip 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.

2.4 Device Description

The subject device Pulse Oximeter is a battery powered device, which can mainly detect and display the measured oxyhemoglobin saturation (SpO_2) and pulse rate (PR) value. Place one fingertip into the photoelectric sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display. The device has 2 display modes. 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), LED 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.

2.5 Comparison list of the technological characteristics

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

Comparison Elements	**Subject Device**	**Predicate Device**	**Similar or Different**
Model	MD300C19	MD300CI218	-
Item	Pulse Oximeter	Fingertip Pulse Oximeter	-
Regulation No.	21 CFR 870.2700	21 CFR 870.2700	√
Classification	II	II	√
Device Classification Name	Oximeter	Oximeter	√
Product Code	DQA	DQA	√
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 is not	The Fingertip Pulse Oximeter MD300CI218 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	Difference 1

Comparison Elements	Subject Device	Predicate Device	Similar or Different
Model	MD300C19	MD300CI218	-
	intended for continuous monitoring, use during motion or use with low perfusion. The device is intended for reuse. The device is wearing on fingertips while using	hospitals, hospital-type facilities and homecare environment.	
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.	Difference 2
Design Principle	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	The fingertip 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 660nm, which is red light; the other is 905nm, which is infrared-red light. Skin, bone, tissue and venous	√

Comparison Elements		**Subject Device**	**Predicate Device**	**Similar or Different**
Model		MD300C19	MD300CI218	-
		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.	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.	
Measurement Wavelength	Red	660±3nm	660±3nm	√
	Infrared	905±10nm	905±10nm	√

Comparison Elements		**Subject Device**	**Predicate Device**	**Similar or Different**
Model		MD300C19	MD300CI218	-
Performance Specification	Display Type	LED	OLED	Difference 3
	User Interface	2 display directions	2 display directions	√
	Power supply	2*AAA alkaline batteries	2*AAA alkaline batteries	√
	Display Data	SpO_2, PR	SpO_2, PR	√
	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	√

Comparison Elements		**Subject Device**	**Predicate Device**	**Similar or Different**
Model		MD300C19	MD300CI218	-
	SpO2 Resolution	1%	1%	√
	PR Display Range	0bpm~255bpm	30bpm~250bpm	Difference 4
	PR Measurement Range	30bpm~250bpm	30bpm~250bpm	√
	PR Accuracy	30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%	30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%	√
	PR Resolution	1bpm	1bpm	√
	Transmitter	NA	Bluetooth Compliance: Version 4.0	Difference 5

Comparison Elements		**Subject Device**	**Predicate Device**	**Similar or Different**
Model		MD300C19	MD300CI218	-
Environment	Operating Temperature	0℃~40℃	5℃~40℃	Difference 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	√
	Enclosure	ABS	ABS	√
	Lens	PMMA	PMMA	√

Comparison Elements		**Subject Device**	**Predicate Device**	**Similar or Different**
Model		MD300C19	MD300CI218	-
	Button	Silica gel pad	ABS	Difference 7
	Fingertip Cushion	Silica gel pad	Silica gel pad	√
Testing	Laboratory Testing	ISO 80601-2-61	ISO 80601-2-61	√
	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	√

- **Difference 1: Indications for use**

  Compared with the intended use of predicate device, the subject device increases the description of the application location, application conditions and use frequency. The subject device has 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. Therefore, this difference does not affect substantially equivalence between subject device and predicate device on safety and effectiveness.

- **Difference 2: Components**

  The components of subject 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 subject device has 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. Therefore, this difference does not affect substantially equivalence between subject device and predicate device on safety and effectiveness.

- **Difference 3: Display Type**

  The subject device has the different display type with the predicate device. The subject device is configured with the LED display; the predicate device is using the OLED display. The varies display type is due to different marked strategy. In addition, the subject device has 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 subject device and predicate device on safety and effectiveness.

- **Difference 4: PR Display Range**

  The subject device has the different pulse rate display range with the predicate device. The subject device pulse rate display range is 0bpm~255bpm which the predicate device is 30bpm~250bpm. The pulse rate display range of the subject device was verified according to IEC 60601-1 and ISO 80601-2-61. All the results can meet the standard requirements. Therefore, this difference does not affect substantially equivalence between subject device and predicate device on safety and effectiveness.

- **Difference 5: Transmitter**

  The subject 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. Therefore, this difference does not affect substantially equivalence between subject device and predicate device on safety and effectiveness.

- **Difference 6: Environment**

  The Operating Temperature of subject device is different with the predicate device and other environment requirements are same. The lower limit operating temperature of subject device is 0℃ which the predicate device is 5℃. However, the operating temperature of subject 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 subject device and predicate device on safety and effectiveness.

- **Difference 7: Contacting Material**

  The contact material of subject device is 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.

2.6 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 is not intended for continuous monitoring, use during motion or use with low perfusion. The device is intended for reuse. The device is wearing on fingertips while using.

2.7 Testing

The Pulse Oximeter MD300C19 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 MD300C19 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
- ISO10993-10:2010 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 II-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 ISO10993-10:2010

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

Clinical Test

The clinical study was conducted in accordance to ISO 14155-1, -2, ISO80601-2-61:2017, and the FDA Guidance Document for Pulse Oximeters. The subject device of this study was to evaluate the SpO2 accuracy performance of the Beijing Choice Electronic Technology Co., Ltd. MD300C19 Pulse Oximeter during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to arterial blood CO-Oximetry. After Institutional Review Board (IRB) approval, 11 healthy adult volunteer subjects (ages 22-44yr, 53-85kg, 152-179cm, with light to dark pigmentation) were included in the study conducted June. 18, 2022 - Aug. 20, 2022 to evaluate the SpO2 accuracy performance of the Beijing Choice Electronic Technology Co., Ltd. MD300C19 Pulse Oximeter.

The SpO2 accuracy performance results showed the Beijing Choice Electronic Technology Co., Ltd. MD300C19 Pulse Oximeter to have an ARMS of 1.5 during steady state conditions over the range of 70-100%.

2.8 Determination of substantial equivalence

The subject device of Pulse Oximeter MD300C19 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.