November 30, 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: K230587
Trade/Device Name: Wrist Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 1, 2023
Received: November 1, 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 (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.

510(k) Number *(if known)*
K230587

Device Name
Wrist Pulse Oximeter

Indications for Use *(Describe)*
The MD300W628 Wrist Pulse Oximeter is a portable, non-invasive device intended to measure, display, store and transfer functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate (PR) of adult, adolescent and child in hospitals, clinics, long-term care, and home use.
The device intended for spot-checking and can be reused, not intended for continuous monitoring, use during motion or use with low perfusion.

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

K230587

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

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Date prepared：February 21, 2023

2.2 Subject Device Information

Regulation Name: Oximeter

Device Trade/Proprietary Name: Wrist Pulse Oximeter

Model: MD300W628

Purpose of submission： 510（k）

Regulation Number: 21 CFR 870.2700

Product Code: DQA

Class: Ⅱ

Panel: Anesthesiology

Intended use：

The MD300W628 Wrist Pulse Oximeter is a portable, non-invasive device intended to measure, display, store and transfer functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate (PR) of adult, adolescent and child in hospitals, clinics, long-term care, and home use.

The device intended for spot-checking and can be reused, not intended for continuous monitoring, use during motion or use with low perfusion.

2.3 Predicate Device

510(k) Number: K172366

Regulation Name: Oximeter

Device Trade/Proprietary Name: Wrist Pulse Oximeter

Model: MD300W314

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 an internally powered device. The main functions of the devices include hemoglobin oxygen saturation (SpO2), pulse rate (PR) measurements and Pulse amplitude index (PAI), data storage and transmission.

Place one fingertip into the sensor for diagnosis and the oxygen saturation (SpO2), pulse rate (PR) measurements and pulse amplitude index (PAI) will appear on the display. The device is normally applied to adult and pediatric patients in hospital and home care environment.

The subject device is composed of following components to achieve the above detection process: power supply module, detector and emitter, signal collection and process module (MCU), OLED display screen and Bluetooth module.

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. 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. The contact duration is greater than 30 days.

The Wrist oximeter wristband is made of Silicone Gel. The contact duration is greater than 30 days.

The Probe is made of Silicone Gel. The contact duration is greater than 24 hours and less than 30 days.

The display screen is made of glass. The contact duration is greater than 30 days.

The button is made of Aluminium alloy. The contact duration is greater than 30 days.

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
Item	Wrist Pulse Oximeter	Wrist Pulse Oximeter	-
Model	MD300W628	MD300W314	-
Regulation No.	21 CFR 870.2700	21 CFR 870.2700	√
Classification	Ⅱ	Ⅱ	√
Regulation Name	Oximeter	Oximeter	√
Product Code	DQA	DQA	√

Comparison Elements	Subject Device	Predicate Device	Similar or Different
Item	Wrist Pulse Oximeter	Wrist Pulse Oximeter	-
Model	MD300W628	MD300W314	-
Indications for Use	The MD300W628 Wrist Pulse Oximeter is a portable, non-invasive device intended to measure, display, store and transfer functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate (PR) of adult, adolescent and child in hospitals, clinics, long-term care, and home use. The device intended for spot-checking and can be reused, not intended for continuous monitoring, use during motion or use with low perfusion.	MD300W314 is a wrist pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, adolescent, child and infant patients. It is intended for spot-check and / or data collection, recording and transmitting. It can be used in sleep labs, long-term care, hospitals and home use.	Difference 1

Comparison Elements	Subject Device	Predicate Device	Similar or Different
Item	Wrist Pulse Oximeter	Wrist Pulse Oximeter	-
Model	MD300W628	MD300W314	-
Design Principle	The Wrist 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 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	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 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	√

Comparison Elements		Subject Device	Predicate Device	Similar or Different
Item		Wrist Pulse Oximeter	Wrist Pulse Oximeter	-
Model		MD300W628	MD300W314	-
		referred to as SpO2.	referred to as SpO2.	
Components		Power supply module, detector and emitter LED, signal collection and processor module, display module, Bluetooth module.	Power supply module, detector and emitter LED, signal collection and processor module, display module, Bluetooth module.	√
The site of application in the body		Fingers	Fingers	√
Measurement Wavelength	Red	660±3nm	660±3nm	√
	Infrared	905±10nm	905±10nm	√

Comparison Elements		Subject Device	Predicate Device	Similar or Different
Item		Wrist Pulse Oximeter	Wrist Pulse Oximeter	-
Model		MD300W628	MD300W314	-
Performance Specification	Display Type	OLED	LCD	Difference 2
	Power supply	Lithium-ion rechargeable battery	Lithium-ion rechargeable battery	√
	Display Data	SPO_2 , PR , PAI	SPO_2 , PR	Difference 3
	SPO_2	SpO2 Display Range: 70%~100% Measurement range: 70%~100% Accuracy: 70%~100%: ±2%; <69%: unspecified.	SpO2 Display Range: 0%~100% Measurement range: 70%~100% Accuracy: 70%~100%: ±2%; <69%: unspecified.	Difference 4
	PR	PR Display Range 30~250bpm Measurement range: 30~250bpm Resolution: 1bpm Accuracy: 30~99bpm, ±2bpm; 100~250bpm, ±2%	PR Display Range 30~255bpm Measurement range: 30~250bpm Resolution: 1bpm Accuracy: 30~99bpm, ±2bpm; 100~250bpm, ±2%	Difference 5

Comparison Elements		Subject Device	Predicate Device	Similar or Different
Item		Wrist Pulse Oximeter	Wrist Pulse Oximeter	-
Model		MD300W628	MD300W314	-
	Pulse amplitude index （PAI）	Display range: 0.1~20.0% Measurement range: 0.3~20.0% Resolution: 0.1% Accuracy: 0.3~1.0% (±0.2digits); 1.1~20.0% (±20%)	NA	Difference 6
	Network	Bluetooth	Bluetooth	√
	Wireless Transmission Range	0~10m	0~10m	√
	Antenna Type	Internal	Internal	√

Comparison Elements		Subject Device	Predicate Device	Similar or Different
Item		Wrist Pulse Oximeter	Wrist Pulse Oximeter	-
Model		MD300W628	MD300W314	-
	Environment Requirements	Operating Temperature: 5°C ~40°C Ambient Humidity: 15%~93%, no condensation Storage Temperature: -25℃~70℃ Ambient Humidity: ≤93% no condensation	Operating Temperature: 5~40℃ Ambient Humidity: 15%~93%, no condensation Storage/Transportation: -25℃~70℃ Ambient Humidity: ≤93% no condensation	√
Contacting Material	Enclosure	ABS	ABS	Difference 7
	Wrist oximeter wrist belt	Silicone	Silicone	
	Fingertip sensor	Silicone	Silicone	

Comparison Elements		Subject Device	Predicate Device	Similar or Different
Item		Wrist Pulse Oximeter	Wrist Pulse Oximeter	-
Model		MD300W628	MD300W314	-
Performance Testing	Laboratory Testing	The laboratory tests include SpO2 and PR accuracy Test, Weak Perfusion Test, High and Low Temperature and Humidity Test, Performance Test After Cleaning and ISO80601-2-61	The laboratory tests include SpO2 and PR accuracy Test, Weak Perfusion Test, High and Low Temperature and Humidity Test, Performance Test After Cleaning and ISO80601-2-61	√
	Electrical Safety	Conformed to IEC60601-1, IEC 60601-1-11	Conformed to IEC60601-1, IEC 60601-1-11	√
	Software and Cybersecurity	Moderate level of concern	Moderate level of concern	√

Comparison Elements		Subject Device	Predicate Device	Similar or Different
Item		Wrist Pulse Oximeter	Wrist Pulse Oximeter	-
Model		MD300W628	MD300W314	-
		Compliance with: FDA Guidance for the content of Premarket Submissions for Software Contained in Medical Devices and, FDA Guidance for Content of Premarket Submission for Management of Cybersecurity in Medical Device	Compliance with: FDA Guidance for the content of Premarket Submissions for Software Contained in Medical Devices and, FDA Guidance for Content of Premarket Submission for Management of Cybersecurity in Medical Device	
		Risk Management in Compliance with ISO14971	Risk Management in Compliance with ISO14971	
	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**

The subject device and predicate device have a similar intended use.

Compared with the predicate device, the subject device is not suitable for infants' patients. 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 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: Display Type**

The subject device has the different display type with the predicate device.

Compared with the predicate device, the subject 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 3: Display Data**

The subject device has the different display data with the predicate device.

Compared with the predicate device, the subject device can display PAI value. It will not affect the safety and effectives of subject device. The test results of PAI value see the System Test Report in the Performance Testing for reference.

- **Difference 4: SPO_2 display range**

The subject device has the different SpO_2 display range with the predicate device.

Compared with the predicate device, the subject device SpO_2 Display Range is 70%~100% which the predicate device is 0%~100%. The SpO_2 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: PR display range**

The subject device has the different PR display range with the predicate device.

Compared with the predicate device, the subject device PR Display Range is 30~250bpm which the predicate device is 30~255bpm. The PR 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 I on safety and effectiveness.

- **Difference 6: Pulse amplitude index （PAI）**

The subject can display PAI test value, but predicate device cannot display this value. It will not affect the safety and effectives of subject device. The test results see the System Test Report in the Performance Testing.

- **Difference 7: Contacting Material**

The contact material of subject device is similar with the predicate device, but the supplier of the material is different. Therefore, the contact materials of the subject device and predicate device are considered to be different. 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 Testing

The Wrist Pulse Oximeter MD300W628 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 Wrist Pulse Oximeter MD300W628 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
- ISO10993-1:2018 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
- ISO10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

We have also conducted other performance test including SpO_2, PR and pulse amplitude index (PAI) accuracy test. Device Output Time and Finger Out Time Test, Device Response Time Test, Weak Perfusion Test, High and Low Temperature & Humidity Test Per **Guidance for Industry and FDA Staff: Pulse Oximeter-Premarket Notification submission [510(k)s]**.

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.

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	Bluetooth Wireless Test according to FCC Part 15B and Part 15C
7	Wireless coexistence testing
8	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ISO10993-1:2018
9	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO10993-5:2009
10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization ISO10993-10:2021

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

Clinical Test

The Clinical Study was conducted at Yue Bei people's Hospital. The study was conducted in accordance to ISO 14155-1, -2, ISO 80601-2-61:2017, 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. MD300W628 Wrist Pulse Oximeter and its supporting M-50G SpO2 Sensor. 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. MD300W628 Wrist Pulse Oximeter and its supporting M-50G SpO2 Sensor.

The SpO2 accuracy performance results showed the Beijing Choice Electronic Technology Co., Ltd. MD300W628 Wrist Pulse Oximeter and its supporting M-50G SpO2 Sensor to have an ARMS of 1.68 during steady state conditions over the range of 70-100%.

2.7 Determination of substantial equivalence

The subject device of Wrist Pulse Oximeter MD300W628 has the same classification information, same intended use, similar performance effectiveness as the predicated device. The subject device is Substantially Equivalent (SE) to the predicate device which is US legally market device.