February 11, 2022

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

Re: K211400
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: February 11, 2022
Received: August 6, 2021

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 and Part 809); 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,

Todd Courtney
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)*
K211400

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.

Respiratory rate (RR) is intended for adults only.

The Pulse Oximeter is intended for use in hospitals, hospital-type facilities and homecare environment.

The Pulse Oximeter is not intended for patients with:
· cardiopulmonary disease
· cardiac dysrhythmias, unstable patients, or patients in the ICU
· respiratory insufficiency or recovering from surgery or trauma
· morbid obesity
· severe arrhythmia

The Pulse Oximeter is not intended for patients who are:
· injured, disabled or physically deformed
· pregnant or lactating
· taking drugs that stain the blood.

The Pulse Oximeter is not designed to detect apneas.

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 III 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.

3.1 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 BEIJING, 100041, P.R.China
- **Contact Person:**
  Haiying Zhao
  Beijing Choice Electronic Technology Co., Ltd.
  North Building 3F, No. 9 Shuangyuan Road,
  Badachu Hi-tech Zone, Shijingshan District
  Beijing China 100041
  Phone: +86-10-88204631
  Fax:861088204632
  Email: cc@choicemmed.com
- **Date prepared：January 6，2022**

3.2 Proposed Device Information

Device Common Name: Pulse Oximeter
Device Trade/Proprietary Name: Pulse Oximeter
Model: MD300CI218R
Classification Name: Oximeter
Regulation Number: 870.2700
Product Code: DQA

Regulatory Class: Class Ⅱ

Panel: Anesthesiology

Premarket Notification 510(k) Submission—Section III 510(k) Summary

3.3 Predicate Device

Elements	Primary Predicate Device	Secondary Predicate Device
510(k) Number	K181956	K181503
Device Name	Masimo MightySat Rx Fingertip Pulse Oximeter	Fingertip Pulse Oximeter
Model	/	MD300CI218
Classification Name	Oximeter	Oximeter
Product Code	DQA,BZQ	DQA
Regulation Number	870.2700	870.2700
Regulatory Class	Class Ⅱ	Class Ⅱ
Panel	Anesthesiology	Anesthesiology
Applicant	Masimo Corporation	Beijing Choice Electronic Technology Co., Ltd.
Indications for Use	The Masimo MightySat Rx Fingertip Pulse Oximeter is intended for hospitals, hospital-type facilities,home environments, and transport. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of respiration rate (RRp) for adult patients.	The 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.

3.4 Device Description

The proposed device Fingertip Pulse Oximeter MD300CI218R is a battery powered device. It can detect and display the measured %SpO2 ,pulse rate,respiratory rate and perfusion index and will automatically power off when there is no signal for longer than 8 seconds. The proposed device is adopted colorful color OLED screen to display SpO2, PR , respiratory rate, perfusion index, and waveform which can be displayed in 2 directions. And it is designed with the battery indicator function to warn the user that the battery power may be low.

The proposed device 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, respiratory rate (RR) for adult in hospitals, hospital-type facilities and homecare environment. And it can transmit the measurements to Smart Device installed the mobile APP via Bluetooth 4.0 to help the users to organize and track their health information.

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

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 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.

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.

The device is software-driven and the software validation is provided in ***software***.

Premarket Notification 510(k) Submission—Section III 510(k) Summary

3.5 Comparison list of the technological characteristics

Table 3-1 Performance Specification Comparison Table between the Proposed Device and Predicate Device

Comparison Elements	Proposed Device	Secondary Predicate Device	Primary Predicate Device
Product Name	Pulse Oximeter	Fingertip Pulse Oximeter	Masimo MightySat Rx Fingertip Pulse Oximeter
Model	MD300CI218R	MD300CI218	Not Specified
Regulation No.	21 CFR 870.2700	21 CFR 870.2700	21 CFR 870.2700
Classification	Ⅱ	Ⅱ	Ⅱ
Classification Name	Oximeter	Oximeter	Oximeter
Product Code	DQA	DQA	DQA,BZQ
Indications for 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. Respiratory rate (RR) is intended for adults only. The Pulse Oximeter is	The 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.	The Masimo MightySat Rx Fingertip Pulse Oximeter is intended for hospitals, hospital-type facilities,home environments, and transport. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients during

Premarket Notification 510(k) Submission—Section III 510(k) Summary

	intended for use in hospitals, hospital-type facilities and homecare environment. The Pulse Oximeter is not intended for patients with: ● cardiopulmonary disease ● cardiac dysrhythmias, unstable patients, or patients in the ICU ● respiratory insufficiency or recovering from surgery or trauma ● morbid obesity ● severe arrhythmia The Pulse Oximeter is not intended for patients who are: ● injured, disabled or physically deformed ● pregnant or lactating ● taking drugs that stain the blood. The Pulse Oximeter is not designed to detect apneas.		both no motion and motion conditions, and for patients who are well or poorly perfused. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of respiration rate (RRp) for adult patients.
Comparison Statement	**The proposed device and the primary predicate device have the same intended use expect that the proposed device can not be used in transport and poor perfused.**		

Premarket Notification 510(k) Submission—Section III 510(k) Summary

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 process module, display module, Bluetooth module, indicator module, user interface.	It includes an OLED color display, enclosed by plastic housing and powered by two alkaline AAA batteries.
Design Principle	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 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	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 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.	The MightySat Rx adopts Masimo SET technology which uses a two-wavelength sensor to measure the indicated parameters based on light absorption principles of oxygenated blood and deoxygenated blood which generates a photoplethysmogram. Respiration rate (RRp) measures the respiration rate by analyzing cyclic variations in the photoplethysmogram due to respiration.

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		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. Respiration rate (RR) measures the respiration rate by analyzing cyclic variations in the photoplethysmogram due to respiration.		
Measurement Wavelength	Red	660±3nm	660±3nm	Not Specified
	Infrared	905±10nm	905±10nm	Not Specified
Comparison Statement		**The proposed device and the primary predicate device have the same design principle.It has identical measurement wavalength as the second predicate device.**		
	Display Type	OLED	OLED	OLED
Perfor	User Interface	2 display directions	2 display directions	2 display directions

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	Power supply	2*AAA alkaline batteries	2*AAA alkaline batteries	2*AAA alkaline batteries
	Display Data	SpO2, PR,Respiratory Rate, Perfusion Index,pulse waveform	SpO2, PR	SpO2, PR,Respiratory Rate,Perfusion Index, Pleth Variability Index
	SpO2 Display Range	0~100%	0%~100%	0%~100%
	SpO2 Measurement Range	70%~100%	70%~100%	70%~100%
	SpO2 Accuracy	70%~100%, ±2%; 0~69% no definition	70%~100%, ±2%; 0~69% no definition	70%~100%, ±2%
	SpO2 Resolution	1%	1%	1%
	PR Display Range	30bpm~250bpm	30bpm~250bpm	25bpm~240bpm
	PR Measurement Range	30bpm~250bpm	30bpm~250bpm	25bpm~240bpm
	PR Accuracy	30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%	30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%	3 BPM ARMS
	PR Resolution	1 BPM	1 BPM	1BPM

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	RR Measurement Range	4-45rpm	NA	4-70
	RR Accuracy	Mean Error:±1rpm	NA	3 RPM ARMS, 1 RPM Mean Error
	Perfusion Index Measurement Range	0.1%-20%	NA	0.02%-20%
	Perfusion Index Resolution	0.1%	NA	Not specified
	Wireless Transmission Range	0~10m	0~10m	Not specified
	Antenna Type	Internal	Internal	Not specified
	Transmitter	Bluetooth Compliance: Version 4.0	Bluetooth Compliance: Version 4.0	Not specified
	Operating Temperature	5℃~40℃	5℃~40℃	5℃~40℃
	Relative Humidity	15% ~93%, no condensation in operation; ≤93% no condensation in storage	15% ~93%, no condensation in operation; ≤93% no condensation in storage	10% to 95%, non-condensing
	Atmosphere Pressure	70kPa~106kpa	70kPa~106kpa	54kPa~106kpa

Premarket Notification 510(k) Submission—Section III 510(k) Summary

Comparison Statement		**The Proposed device has similar product specification as the primary predicate device . The proposed device and the secondary predicate device have identical product specification except that the proposed device can measure PI and RR.**		
Contacting Material	Battery Cover	ABS	ABS	Not specified
	Enclosure			
	Power Button			
	Fingertip Cushion	Silicone Gel	Silicone Gel	Not specified
Comparison Statement		**The contacting materials of the proposed device are same to those of the secondary predicate device.**		
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	Mechanical and environmental testing, 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	Conformed to IEC60601-1, IEC 60601-1-11

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EMC and Electrical Safe	Electromagnetic Compatibility	Conformed to IEC60601-1-2 Conformed to FCC certification	Conformed to IEC60601-1-2 Conformed to FCC certification	Conformed to IEC60601-1-2 Conformed to FCC certification
Software and Cybersecurity		Moderate level of concern	Moderate level of concern	Moderate level of concern
		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	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	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	Compliance with the Guidance of pulse oximeter-premarket notification issued on March 4,2013

3.6 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, respiratory rate (RR) for adult in hospitals, hospital-type facilities and homecare environment.

3.7 Performance data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility testing of the patient contacted materials used in the proposed device have been conducted according to the requirement of ISO 10993-1, ISO 10993-5, ISO 10993-10.

Electrical safety and electromagnetic compatibility (EMC)

We have conducted IEC 60601-1,IEC 60601-1-11,IEC 60601-1-2,ISO 80601-2-61 test for the proposed device.

We have also conducted other performance test including SpO2 Accuracy Test, PR Accuracy Test, Reperatory Rate Test , Perfusion Index Test Device, Output Time and Finger Out Time Test, Device Response Time Test, , High and Low Temperature & Humidity Test Per **Guidance for Industry and FDA Staff: Pulse Oximeter-Premarket Notification submission [510(k)s]**.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Wireless Testing

The hardare of the proposed device is same to those of the secondary predicate device

which was cleared in October 11,2018 by FDA. So testing reports performed and submitted with K181503 with repect to FCC and wireless coexistence also apply to the proposed device.

Clinical Test

In K181503, Choice include the clinical test of the secondary predicate device for the SpO2 measurement. Because there was no change in SpO2 measurement function of the device as part of this submission, the clinical study for SpO2 was not repeated.

For this submission to add the Respiratory Rate,Choice performed clinical test to validate the performance of Respiratory Rate. Choice conduted the clinial test on 11 heathy adult volunteer subjects and 22 patient. There were no adverse events during the study. The results of clinical study of respiratory rate is that the Mean Error is ± 1 and the Root mean square error is ≤ 2.The clinical study report was presented in Performance Testing-Clinical Study Report.

3.8 Conclusion

The proposed device has the same classification information, same intended use, similar design principle as the primary predicated device. The hardware of the proposed device is same as the secondary predicate device . The results of the testing demonstrate that all requirements and performance specifications were satisfied and the subject device is substantially equivalent to its predicate.