



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

Re: K181503
Trade/Device Name: Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 4, 2018
Received: September 4, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section II Indications for Use Statement

Indications for Use

510(k) Number (if known): K181503

Device Name: Fingertip Pulse Oximeter MD300CI218

Indications for Use:

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.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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.
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100143 Beijing, P.R.China
- **Contact Person:**
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Email: cc@choicemed.com
- **Date prepared : June 04, 2018**

3.2 Proposed Device Information

Device Common Name: Pulse Oximeter
Device Trade/Proprietary Name: Fingertip Pulse Oximeter
Model: MD300CI218
Classification Name: Oximeter
Regulation Number: 870.2700
Product Code: DQA
Class: II
Panel: Anesthesiology

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3.3 Predicate Device

510(k) Number: K142888

Common Name: Pulse Oximeter

Device Trade/Proprietary Name: Fingertip Pulse Oximeter

Model: MD300C318T2

Classification Name: Oximeter

Product Code: DQA

Regulation Number: 870.2700

Device Class: II

Panel: Anesthesiology

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.

Intended Use: The MD300C318T2 is intended for spot checking in measuring and displaying functional arterial hemoglobin (SpO₂) and pulse rate. It is intended for adult, adolescent, child and infant users in hospitals, hospital facilities and home healthcare environments.

3.4 Device Description

The proposed device Fingertip Pulse Oximeter MD300CI218 is a battery powered device. It can detect and display the measured %SpO₂ and pulse rate value 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 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 normally applied to adult, adolescent, child and infant patients in hospitals, hospital 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

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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*.

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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	Predicate Device
Product Name	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter
Model	MD300CI218	MD300C318T2
Regulation No.	21 CFR 870.2700	21 CFR 870.2700
Classification	II	II
Classification Name	Oximeter	Oximeter
Product Code	DQA	DQA
Indications for Use	The 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 hospitals, hospital-type facilities and homecare environment.	The MD300C318T2 is intended for spot checking in measuring and displaying functional arterial hemoglobin (SpO ₂) and pulse rate. It is intended for adult, adolescent, child and infant users in hospitals, hospital facilities and home healthcare environments.
Comparison Statement	The proposed device and the predicated device have the same intended use and classification	
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.

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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 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 .	Principle of the oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO ₂) in red and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.
Measurement Wavelength	Red	660 ± 3nm	660nm
	Infrared	905 ± 10nm	940nm
Comparison Statement		The proposed device and the predicate device have the same design principle and similar measurement wavelength. The only difference is the wavelength of the infrared LED emitter, and we can verify that which will not effect the essential performance of the proposed device.	
	Display Type	OLED	OLED

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Performance Specification	User Interface	2 display directions	2 display directions
	Power supply	2*AAA alkaline batteries	2*AAA alkaline batteries
	Display Data	SpO2, PR	SpO2, PR
	SpO2 Display Range	0~100%	0%~100%
	SpO2 Measurement Range	70%~100%	70%~100%
	SpO2 Accuracy	70%~100%, $\pm 2\%$; 0~69% no definition	70%~100%, $\pm 2\%$; 0~69% no definition
	SpO2 Resolution	1%	1%
	PR Display Range	30bpm~250bpm	0bpm~235bpm
	PR Measurement Range	30bpm~250bpm	30bpm~235bpm
	PR Accuracy	30bpm~99bpm, $\pm 2\text{bpm}$; 100bpm~250bpm, $\pm 2\%$	30bpm~99bpm, $\pm 2\text{bpm}$; 100bpm~235bpm, $\pm 2\%$
	PR Resolution	1%	1%
	Wireless Transmission Range	0~10m	0~10m
	Antenna Type	Internal	Internal
Transmitter	Bluetooth Compliance: Version 4.0	Bluetooth Compliance: Version 2.1	

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	Operating Temperature	5°C~40°C	5°C~40°C
	Relative Humidity	15% ~93%, no condensation in operation; ≤93% no condensation in storage	15% ~93%, no condensation in operation; ≤93% no condensation in storage
	Atmosphere Pressure	70kPa~106kpa	86kPa~106kpa
Comparison Statement		The proposed device has similar product specification as predicate device.	
Contacting Material	Battery Cover	ABS	ABS
	Enclosure		
	Power Button		
	Fingertip Cushion	Medical Silicone Gel	Medical Silicone Gel
Comparison Statement		The contacting materials of the proposed device are same to those of the 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
	Electrical Safety	Conformed to IEC60601-1, IEC 60601-1-11	Conformed to IEC60601-1, IEC 60601-1-11

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EMC and Electrical Safety	Electromagnetic Compatibility	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 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 ISO14971:2007	Moderate level of concern Compliance with FDA Guidance for the content of Premarket Submissions for Software Contained in Medical Devices Risk Management in Compliance with ISO14971:2007
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	

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3.6 Intended use

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.

3.7 Testing

The Fingertip Pulse Oximeter MD300CI218 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 Fingertip Pulse Oximeter MD300CI218 is designed and tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

IEC60601-1:2005+A1:2012 Medical Electrical Equipment-Part 1: General Requirements for Safety.

IEC 60601-1-11:2010 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 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic disturbances - Requirements and tests.

ISO 80601-2-61:2011 Medical Electrical Equipment- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

We have also conducted other performance test including SpO₂ and PR 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.

The list of non-clinical test performed on the proposed devices.

No.	Test Name
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1	System Performance Test
2	Performance Test according to ISO 80601-2-61
3	Electromagnetic Compatibility Test According to IEC 60601-1-2
4	Electrical Safety Test According to IEC 60601-1
5	Used in the home healthcare environment test according to IEC 60601-1-11
6	Bluetooth Wireless Test according to FCC Part 15B and Part 15C
7	wireless coexistence testing

The test results indicate that the effectiveness of the proposed device is identical to that of the predicate device.

Clinical Test

The clinical study of MD300CI218 was conducted following the testing described in clause 201.12.1 of ISO 80601-2-61:2011 Medical electrical equipment- Part 2-61 Particular requirements for basic safety and essential performance of pulse oximeter equipment.

The Clinical Study of MD300CI218 was conducted Mar.9-11,2018 in the Yue Bei people's Hospital, cardiovascular medicine in accordance with the study procedure. There were no deviations from the study procedure. Institutional Review Board(IRB) approval was obtained for testing through the Yue Bei People's Hospital-IRB. 12 healthy adult subjects, gave their informed consent and were studied. The clinical study report was presented in *Performance Testing-Clinical Study Report*.

Subjects information:

There were no adverse events during the study. The subject demographics included a total of 12 healthy adult volunteer subjects,7 females and 5 males. The ages ranged from 18 to 45years. The subject weights ranged from 42 to 83kg. The subject Height ranged from 153 to 179cm. The Skin tones included in the study were as follows: 4 subjects with very dark pigmentation, 1 subject with very light pigmentation. The remaining subjects with light skin tones of China origins.

Results:

The SpO₂ accuracy performance results showed the MD300CI218 Fingertip Pulse Oximeter to have an Arms of 1.66 during steady state conditions over the range of 70-100%.

Conclusion:

The results of the study provide supporting evidence that the pulse oximeter MD300CI218 Fingertip Pulse Oximeter was compliance to the accuracy specification claimed by the manufacturer.

The clinical statement was presented in *Performance Testing-Clinical Statement*.

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3.8 Determination of substantial equivalence

The proposed device of Fingertip Pulse Oximeter MD300CI218 has the same classification information, same intended use, same design principle, similar product design and specifications, same performance effectiveness as the predicated device. The main difference is the wavelength of the infrared LED emitter, and we can verify that which will not affect the essential performance of the proposed device. So the proposed devices are Substantially Equivalent (SE) to the predicate device which is US legally market device.