



Food and Drug Administration
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August 28, 2015

Beijing Choice Electronic Technology Co., Ltd.
Lei Chen
Quality Director
No. 9 Shuangyuan Road, Badachu Hi-tech Zone
Shijingshan District
Beijing, 100041
CHINA

Re: K151206

Trade/Device Name: Fingertip Pulse Oximeter MD300C208/MD300C198

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: Class II

Product Code: DQA

Dated: July 17, 2015

Received: July 24, 2015

Dear Mr. Chen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
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Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151206

Device Name

Fingertip Pulse Oximeter MD300C208/MD300C198

Indications for Use (Describe)

The Fingertip Pulse Oximeter MD300C208/MD300C198 is a non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult, adolescent and child patients in hospitals and hospital facilities.

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.

The assigned 510(k) number is **K151206** .

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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- **Date prepared : August 28, 2015**

3.2 Proposed Device Information

Device Common Name: Pulse Oximeter

Device Trade/Proprietary Name: Fingertip Pulse Oximeter

Model: MD300C208, MD300C198

Classification Name: Oximeter

Regulation Number: 870.2700

Product Code: DQA

Class: II

Panel: Anesthesiology

3.3 Predicate Device

510(k) Number: K140682

Common Name: Pulse Oximeter

Device Trade/Proprietary Name: Fingertip Pulse Oximeter

Model: MD300C29-H

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 Fingertip Pulse Oximeter MD300C29-H is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult, adolescent and child patient in hospital.

3.4 Device Description

The Fingertip Pulse Oximeter features low power consumption, convenient operation and portability. Place one fingertip into the photoelectric sensor for diagnosis and the pulse rate and oxygen saturation will appear on the display.

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 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.

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

3.5 Comparison list of the technological characteristics

Table 3-1 Performance Specification Comparison Table between the Proposed Device (MD300C208) and Predicate Device

Comparison Elements	Proposed Device	Predicate Device
Product Name	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter
Model	MD300C208	MD300C29-H
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 Fingertip Pulse Oximeter MD300C208 is a non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate of adult, adolescent and child patients in hospitals and hospital facilities.	The Fingertip Pulse Oximeter MD300C29-H is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate of adult, adolescent and child patient in hospital.
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.	detector and emitter LED, signal amplify unit, CPU, data display unit and power unit

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Design Principle		The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 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 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.
Measurement Wavelength	Red	660 ± 3nm	660 ± 3nm
	Infrared	905 ± 8nm	905 ± 8nm
Comparison Statement		The proposed device and the predicate device have the same design principle and similar measurement wavelength. The only difference is that the proposed device adds the Bluetooth module in the product components, and we can verify which will not affect the basic safety and essential performance of the proposed device.	
	Display Type	OLED	OLED

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	Working Time	Approximately 28 hours of continuous monitoring	Approximately 25 hours of continuous monitoring
Performance Specification	User Interface	2 display directions and 2 displayed parameters	6 directions for display
	Power supply	2*AAA alkaline batteries	2*AAA alkaline batteries
	Display Data	SpO2, PR, Pulse Amplitude	SpO2 ,PR
	SpO2 Display Range	35%~100%	35%~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	30bpm~250bpm
	PR Measurement Range	30bpm~250bpm	30bpm~250bpm
	PR Accuracy	30bpm~99bpm, $\pm 2\text{bpm}$; 100bpm~250bpm, $\pm 2\%$	30bpm~99bpm, $\pm 2\text{bpm}$; 100bpm~250bpm, $\pm 2\%$
	PR Resolution	1%	1%
Operating Temperature	5°C ~40°C	5°C ~40°C	

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	Relative Humidity	≤80% no condensation in operation; ≤93% no condensation in storage	≤80% no condensation in operation; ≤93% no condensation in storage
	Atmosphere Pressure	86kPa~106kpa	86kPa~106kpa
Comparison Statement		The proposed device has similar product specification as predicate device.	
Contacting Material	Battery Cover	ABS	ABS
	Enclosure		
	Fingertip Cushion	Laser Etching Medical Silicone Gel	Laser Etching Medical Silicone Gel
	Power Button		
	Coating	Inks	Inks
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	Meet the requirements of FDA Guidance
	Electrical Safety	Conformed to IEC60601-1	Conformed to IEC60601-1

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EMC and Electrical Safe	Electromagnetic Compatibility	Conformed to IEC60601-1-2 Conformed to FCC certification	Conformed to IEC60601-1-2
	Software	Moderate level of concern	Moderate level of concern
		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
		Risk Management in Compliance with ISO14971:2007	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 FDA guidance	

Table 3-2 Performance Specification Comparison Table between the Proposed Device (MD300C198) and Predicate Device

Comparison Elements	Proposed Device	Predicate Device
Product Name	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter
Model	MD300C198	MD300C29-H
Regulation No.	21 CFR 870.2700	21 CFR 870.2700
Classification	II	II
Classification Name	Oximeter	Oximeter

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Product Code	DQA	DQA
Indications for Use	The Fingertip Pulse Oximeter MD300C198 is a non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, adolescent and child patients in hospitals and hospital facilities.	The Fingertip Pulse Oximeter MD300C29-H is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, adolescent and child patient in hospital.
Comparison Statement	The proposed device and the predicated device have the same intended use and classification	
Components	detector and emitter LED, signal amplify unit, CPU, data display unit and power unit, Bluetooth module	detector and emitter LED, signal amplify unit, CPU, data display unit and power unit
Design Principle	The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 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	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

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		absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.	increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.
Measurement Wavelength	Red	660 ± 3nm	660 ± 3nm
	Infrared	905 ± 8nm	905 ± 8nm
Comparison Statement		The proposed device and the predicate device have the same design principle and similar measurement wavelength. The only difference is that the proposed device adds the Bluetooth module in the product components, and we can verify which will not affect the basic safety and essential performance of the proposed device.	
	Display Type	LED	OLED
	Working Time	Approximately 24 hours of continuous monitoring	Approximately 25 hours of continuous monitoring
Performance Specification	User Interface	2 directions for display	6 directions for display
	Power supply	2*AAA alkaline batteries	2*AAA alkaline batteries
	Display Data	SpO2, PR	SpO2 ,PR
	SpO2 Display Range	35%~99%	35%~100%
	SpO2 Measurement Range	70%~99%	70%~100%
	SpO2 Accuracy	70%~99%, ±2%; 0~69% no definition	70%~100%, ±2%; 0~69% no definition
	SpO2 Resolution	1%	1%

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	PR Display Range	30bpm~250bpm	30bpm~250bpm
	PR Measurement Range	30bpm~250bpm	30bpm~250bpm
	PR Accuracy	30bpm~99bpm, ± 2 bpm; 100bpm~250bpm, $\pm 2\%$	30bpm~99bpm, ± 2 bpm; 100bpm~250bpm, $\pm 2\%$
	PR Resolution	1%	1%
	Operating Temperature	5°C~40°C	5°C~40°C
	Relative Humidity	$\leq 80\%$ no condensation in operation; $\leq 93\%$ no condensation in storage	$\leq 80\%$ no condensation in operation; $\leq 93\%$ no condensation in storage
	Atmosphere Pressure	86kPa~106kpa	86kPa~106kpa
Comparison Statement		The proposed device has similar product specification as predicate device.	
Contacting Material	Battery Cover	ABS	ABS
	Enclosure		
	Fingertip Cushion	Laser Etching Medical Silicone Gel	Laser Etching Medical Silicone Gel
	Power Button		
	Coating	Inks	Inks
Comparison Statement		The contacting materials of the proposed device are same to those of the predicate device.	

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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	Meet the requirements of FDA Guidance
	Electrical Safety	Conformed to IEC60601-1	Conformed to IEC60601-1
EMC and Electrical Safe	Electromagnetic Compatibility	Conformed to IEC60601-1-2 Conformed to FCC certification	Conformed to IEC60601-1-2
Software		Moderate level of concern	Moderate level of concern
		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
		Risk Management in Compliance with ISO14971:2007	Risk Management in Compliance with ISO14971:2007

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

Label and Labeling	Compliance with the Guidance of pulse oximeter-premarket notification issued on March 4,2013	Compliance with FDA guidance
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3.6 Intended use

The Fingertip Pulse Oximeter MD300C208/MD300C198 is a non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult, adolescent and child patients in hospitals and hospital facilities.

3.7 Testing

The Fingertip Pulse Oximeter MD300C208 and MD300C198 were 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 MD300C208/MD300C198 is designed and tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

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

IEC60601-1-2:2007 Medical Electrical Equipment-Part1-2: General requirements for safety, Collateral standard: Electromagnetic compatibility -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.

All clauses are assessed to comply with the requirement of ISO 80601-2-61:2011(First Edition) for use with IEC60601-1:2005 (Third Edition) +CERR.1(2005)+CORR.2(2007). Excluded the following clauses:

The following clauses/collaterals were excluded from this testing:

201.7.9.2.14.101c) biocompatibility

201.10 Protection against unwanted and excessive radiation HAZARDS

201.12 ACCURACY of controls and instruments and protection against hazardous outputs

201.15.3.5.101.2 Shock and vibration for professional transport

202 EMC

208 Alarm

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]**.

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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
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	Bluetooth Wireless Test according to FCC Part 15B and Part 15C

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

3.8 Determination of substantial equivalence

The proposed device of Fingertip Pulse Oximeter MD300C208/MD300C198 has the same classification information, similar intended use, same design principle, similar product design and specifications, and the same performance as the predicated device. The main differences are the proposed devices have function of Bluetooth and MD300C208 can display Pulse Amplitude while the predicate device does not have these function. The differences are slight and do not influence the effectiveness and safety of the device. According to the test results, the proposed device is as safe as effective and performance as well as the predicate device. So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.