DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 5, 2016

Beijing Choice Electronic Technology Co., Ltd.
Lei Chen
Quality Director
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Shijingshan District
Beijing, 100041
CHINA

Re: K161560
Trade/Device Name: Fingertip Pulse Oximeter MD300CN310
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: August 25, 2016
Received: August 29, 2016

Dear Lei 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

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): K161560

Device Name: Fingertip Pulse Oximeter MD300CN310

Indications for Use:

The Fingertip Pulse Oximeter MD300CN310 is a handheld 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, hospital-type facilities and homecare.

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)

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 K161560 .

3.1 Submitter Information

- **Manufacturer Name:**
  Establishment Registration Number: 3005569927
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  100143 Beijing, P.R.China
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- **Date prepared：September 19, 2016**

3.2 Proposed Device Information

Device Common Name: Pulse Oximeter
Device Trade/Proprietary Name: Fingertip Pulse Oximeter
Model: MD300CN310
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 proposed device Fingertip Pulse Oximeter MD300CN310 is a battery powered device, which can detect and display the measured %SpO2 and pulse rate value. The device is adopted dual color OLED screen to display SpO2 and pulse rate value, pulse bar and waveform. The device has 6 display modes. The device is normally applied to adult, adolescent and child patients in hospitals, hospital facilities and homecare environment.

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

Principle of the oximeter is as follows:

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.

The device is software-driven and software validation is provided in ***Section XI Software***.

3.5 Comparison list of the technological characteristics

Table 3-1 Performance Specification Comparison Table between the Proposed Device (MD300CN310) and Predicate Device

Comparison Elements	**Proposed Device**	**Predicate Device**
Product Name	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter
Model	MD300CN310	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 MD300CN310 is a handheld 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, hospital-type facilities and homecare.	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 classification and similar intended use. The difference exists that the proposed device can be used in the homecare environment while the predicate device can not.**	
Components	detector and emitter LED, signal amplify unit, CPU, data display unit and power unit	detector and emitter LED, signal amplify unit, CPU, data display unit and power unit
Design Principle	The pulse oximeter works by applying a	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.	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±10nm	905±8nm
Comparison Statement		**The proposed device and the predicate device have the same design principle and measurement wavelength.**	
	Display Type	OLED	OLED

	Working Time	Approximately 24 hours of continuous operation	Approximately 25 hours of continuous operation
Performance Specification	User Interface	6 display modes	6 directions for display
	Power supply	2*AAA alkaline batteries	2*AAA alkaline batteries
	Display Data	SpO2, PR	SpO2 ,PR
	SpO2 Display Range	0%~100%	35%~100%
	SpO2 Measurement Range	70%~100%	70%~100%
	SpO2 Accuracy	70%~100%, ±2%; 0~69% no definition	70%~100%, ±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, ±2bpm; 100bpm~250bpm, ±2%	30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%
	PR Resolution	1%	1%

	Operating Temperature	5℃~40℃	5℃~40℃
	Storage/Transport temperature	-25℃~70℃	-40℃~55℃
	Relative Humidity	15%~93% no condensation in operation; ≤93% no condensation in storage/transport	≤80% 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		
	Fingertip Cushion	Laser Etching Medical Silicone Gel	Laser Etching Medical Silicone Gel
	Power Button		
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, IEC 60601-1-11	Conformed to IEC60601-1
EMC and Electrical Safe	Electromagnetic Compatibility	Conformed to IEC60601-1-2:2014	Conformed to IEC60601-1-2:2007
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

3.6 Intended use

The Fingertip Pulse Oximeter MD300CN310 is a handheld 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, hospital-type facilities and homecare.

3.7 Testing

The Fingertip Pulse Oximeter MD300CN310 was supported by laboratory 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 MD300CN310 is designed and tested and will be manufactured in accordance with both mandatory and voluntary standards, including:
IEC 60601-1:2012 Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2014 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic disturbances - Requirements and tests.

IEC 60601-1-11:2010 Medical Electrical Equipment Part 1-11: General requirements for basic safety and essential performance-Collateral Standard: Requirements for mrdical electrical equipment and medical electrical systems used in the home healthcare environment.

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
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

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 MD300CN310 has the same classification information, similar intended use, same design principle, similar product design and specifications as the predicated device. The main difference is that the proposed device can be used in the home healthcare environment while the predicate device can not. And we have conducted test according 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. According to the test results, the proposed device is as safe and as effective as the predicate device. So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.