DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 14, 2016

Beijing Choice Electronic Technology Co., Ltd.
Lei Chen
Quality Director
North Building 3F, No 9. Shuangyuan Road
Badachu Hi-tech Zone, Shijingshan District
Beijing, 100041
CHINA

Re: K160268
Trade/Device Name: Fingertip Pulse Oximeter MD300CG11/MD300CG51
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 13, 2016
Received: September 16, 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 Indication for Use Statement

Indication for Use

510(k) Number (if known): ___K160268_____

Device Name: Fingertip Pulse Oximeter MD300CG11/MD300CG51

Indications for Use:

The Fingertip Pulse Oximeter MD300CG11/MD300CG51 is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, adolescent, child and infant patient with the fingers between 0.9 - 2.2 cm (0.4 - 0.9 inch) thick in hospital.

Prescription Use ___√_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (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 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(K) number is K160268

3.1 Date of Submission: Sep. 13, 2016

3.2 Sponsor Information

Establishment Registration Number: 3005569927
Beijing Choice Electronic Technology Co., Ltd.
Room 4104, No.A12 Yuquan Road, Haidian District,
Beijing 100143, P.R.China

Contact Person:
Mr. Lei Chen
Beijing Choice Electronic Technology Co., Ltd.
North Building 3F, No.9 Shuangyuan Road,
Badachu Hi -tech Zone, Shijingshan District,
Beijing, P.R. China, 100041
Phone: +86-10-88798300 Ext 6020
Fax: 215-4052545

3.3 Proposed Device Information

Device Common or Usual Name: Pulse Oximeter
Device Trade or Proprietary Name: Fingertip Pulse Oximeter
Model: MD300CG11/MD300CG51
Classification Name: Oximeter
Product Code: DQA
Regulation Number: 870.2700
Panel: Anesthesiology
Class: II

3.4 Predicate Device

510(k) Number: K131047
Common Name: Oximeter
Device Trade or Proprietary Name: Fingertip Pulse Oximeter
Model: MD300CB3
Classification Name: Oximeter

Device Class: II
Product Code: DQA
Regulation Number: 870.2700
Review Panel: Anesthesiology

3.5 Device Description

The proposed devices Fingertip Pulse Oximeter MD300CG11/MD300CG51 are battery powered devices, which can detect and display the measured %SpO_2 and pulse rate working 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 940nm, 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. The devices are normally applied to adult, adolescent, child and infant in hospital and home environments.

The Proposed devices MD300CG11 and MD300CG51 consist of power supply module, detector and emitter LED, signal collection and process module, display module, user interface and button control circuit.

The proposed devices Fingertip Pulse Oximeter MD300CG11/MD300CG51 share the same measurement principle, structure design, electro-optical components，SpO2 module and equivalent sensor characteristics. The differences among each model of the proposed devices are shown in the table 3-1.

Table 3-1

	MD300CG11	MD300CG51
Display Screen Type	LED	LCD
Display Mode	1 direction for display	2 direction for display
Appearance	Blue top shell	Blue top shell

The proposed devices are not for life-supporting or life-sustaining, not for implant and not sterile. They are reusable and do not need sterilization or re-sterilization.

The devices are for prescription.

The devices do not contain drug or biological products.

3.6 Intended Use

The Fingertip Pulse Oximeter MD300CG11/MD300CG51 is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, adolescent, child and infant patient with the fingers between 0.9 - 2.2 cm (0.4 - 0.9 inch) thick in hospital.

3.7 Technological Characteristics Comparison:

Characteristic	Proposed Device	Predicate Device
Product Name	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter(K131047)
Model	MD300CG11/MD300CG51	MD300CB3
Intended Use	The Fingertip Pulse Oximeter MD300CG11/ MD300CG51 is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, adolescent, child and infant patient with the fingers between 0.9 - 2.2 cm (0.4 - 0.9 inch) thick in hospital.	The Fingertip Pulse Oximeter MD300CB3 is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult, adolescent, child and infant patient in hospital.
Design Principle	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.	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.
Components	The Proposed devices MD300CG11 and MD300CG51 consist of power supply module, detector and emitter LED, signal collection and process module, display module, user interface and button control circuit.	Power supply module, detector and emitter LED, signal collection and process module, display module, user interface and button control circuit
Power	Internal powered equipment	Internal powered equipment

		1 AAA-size alkaline battery	1 AAA-size alkaline battery
Display Screen Type		MD300CG11: LED MD300CG51: LCD	OLED
Display Mode		MD300CG11: 1 direction for display MD300CG51: 2 directions for display	6 directions for display
Interface Display		MD300CG11: SpO2, PR, Pulse bar graph, Low power indicator MD300CG51: SpO2, PR, Pulse bar graph, Low power indicator	SpO2, PR, SpO2 Waveform, Pulse bar graph, Low power indicator
LED Specification	RED	660±2nm	660±2nm
	IR	940±10nm	940±10nm
SpO_2	Display Range	0-99%	0-100%
	Measurement Range	70-99%	70-100%
	Accuracy	70%-99%: ±2%; 0%-69% no definition	70%-100%: ±2%; 0%-69% no definition
	Resolution	1%	1%
PR	Display Range	0-254BPM	0-254BPM
	Measurement Range	30-235BPM	30-235BPM
	Accuracy	30-99bpm, ±2bpm; 100-235bpm, ±2%	30-99bpm, ±2bpm; 100-235bpm, ±2%
	Resolution	1bpm	1bpm
Patient Contacting Material		Medical silicone gel	Medical silicone gel

	ABS plastic	
Material of Shell	Medical silicone gel ABS plastic	Medical silicone gel

3.8 Test Conclusion

Non-clinical Test

The Fingertip Pulse Oximeter MD300CG11/MD300CG51 is designed and tested and will be manufactured in accordance with the following standards, including:

- *IEC 60601-1:2005 Medical Electrical Equipment – Part1: General requirements for safety.*
- *IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1: General requirements for safety-2, Collateral Standard: Electromagnetic compatibility – Requirements and tests.*
- *ISO 80601-2-61:2011 Medical electrical equipment – part2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment*
- *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*

We have conducted performance test for the proposed device in accordance with ISO 80601-2-61. We have also conducted other performance tests for proposed device, including SpO_2 and PR range & accuracy Test, Weak Perfusion Test, High and Low Temperature & Humidity Test, Performance Test after Disinfection, Shelf-life Test per Guidance for Industry and FDA Staff: Pulse Oximeters – Premarket Notification Submissions [510(k)s]. The test reports are presented in ***Performance Testing***.

The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. We have conducted the cytotoxicity, sensitization, and irritation tests which are in compliance with the standards of ISO 10993, “Biological Evaluation of Medical Devices”.

The Software Validation is in compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Clinical Test

The proposed device MD300CG11/MD300CG51 and the predicate device MD300CB3 have the same electro-optical component, SpO2 module and have equivalent sensor characteristics. We state that clinical testing is not necessary because the differences between the subject and predicate devices do not affect calculation of SpO2.

3.9 Determination of substantial equivalence

The proposed device has the same classification information, similar intended use, same design principle, similar product design and specifications, same performance effectiveness as the predicate device. So the proposed devices are Substantially Equivalent (SE) to the

predicate device which is US legally market device.