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

August 13, 2014

Beijing Choice Electronic Technology Co., Ltd.
Mr. Lei Chen
North Building 3F, No.9 Shuangyuan Road,
Badachu Hi-tech Zone, Shijingshan District,
Beijing, P.R. China, 100041

Re: K141128
Trade/Device Name: Fingertip Pulse Oximeter MD300CL37
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 13, 2014
Received: May 15, 2014

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -S

Erin I. Keith, M.S.
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): ___K141128___

Device Name: _Fingertip Pulse Oximeter MD300CL37_

Indications for Use:

The Fingertip Pulse Oximeter MD300CL37 is a portable, 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 home environments.

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 510(k) summary 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.
  Room 320,West Building 4, No.83 FuXing Road
  Beijing 100039, 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 China 100041
  Phone: +86-10-88798300 Ext 6020
  Fax:215-4052545
  Email: cc@choicemmed.com
- **Date prepared：Mar.25, 2014**

3.2 Proposed Device Information

Device Common Name: Pulse Oximeter
Device Trade/Proprietary Name: Fingertip Pulse Oximeter
Model: MD300CL37
Classification Name: Oximeter
Regulation Number: 870.2700
Product Code: DQA
Class: Ⅱ
Panel: Anesthesiology

3.3 Predicate Device

510(k) Number: K123871
Common Name: Pulse Oximeter

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

Device Trade/Proprietary Name: Fingertip Pulse Oximeter
Model: MD300CF315
Classification Name: Oximeter
Product Code: DQA
Regulation Number: 870.2700
Device Class: Ⅱ
Panel: Anesthesiology
Manufacturer: Beijing Choice Electronic Technology Co., Ltd.

3.4Device Description

The proposed device of Fingertip Pulse Oximeter MD300CL37 is a battery powered fingertip device, which can detect, display the measured %SpO_2 and pulse rate value. The device is normally applied to adult, adolescent, child and infant patient in hospitals, hospital-type facilities, and home environments.

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

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 940nm, which is ultra red light. Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photodetector 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 power sources of the proposed device are 2 AAA alkaline batteries. The proposed device have low battery voltage indicator function and the proposed device will automatically power off when there is no signal for longer than 8 seconds. When the finger is placed into the device, the device will be powered on automatically.

The proposed device is not for life-supporting or life-sustaining, not for implant. The device or transducers are not sterile and the transducer is reusable and does not need sterilization or 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 Section of Software.

3.5 Comparison list of the technological characteristics

Table 3-1 Performance Specification Comparison

Comparison Elements	**Proposed Device**	**Predicate Device**
Product Name	Fingertip Pulse Oximeter	Fingertip Pulse Oximeter(K123871)
Model	MD300CL37	MD300CF315
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 is a portable non-invasive device intended for spot-checking of arterial hemoglobin oxygen saturation(SpO_2) and pulse rate of adult, adolescent, child and infant patient in hospitals, hospital-type facilities, and home environments.	The Fingertip Pulse Oximeter is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care etc).
Comparison Statement	**The proposed device has the same indications for use and classification as the predicate device.**	
Components	The proposed device consists of detector and emitter LED, signal amplify unit, CPU, data display unit and power unit	power supply module, detector and emitter LED, signal collection and process module, display module, user interface, voice module and button control circuit.
Design Principle	The pulse oximeter works by applying a	The pulse oximeter works by applying a

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

		sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red light; the other is 940 nm, which is ultra 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.	sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red light; the other is 940 nm, which is ultra 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	660nm	660nm
	Infrared	940nm	940nm
Comparison Statement		**The proposed device has the same design and similar components as the predicate device.**	
Device specification	Display Type	OLED	OLED
	Power Supply	2 AAA-size alkaline batteries	2AAA-size alkaline batteries
	Display Data	SpO2 , PR	SpO2 , PR
	SpO2 display	0～99%	0～99%

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

	range		
	Measurement range	70-99%	70～99%
	Accuracy	70%～99%: ±3%; 0%～69% no definition	70%～99%: ±3%; 0%～69% no definition
	Resolution	1%	1%
	PR display range	0～235BPM	0～254BPM
	PR measurement range	30-235 BPM	30-235 BPM
	PR Accuracy	30～99bpm, ±2bpm; 100～235bpm, ±2%	30～99bpm, ±2bpm; 100～235bpm, ±2%
	Resolution	1bpm	1bpm
	Operating Temperature	5～40℃	5～40℃
	Storage Temperature	-25～+70℃	-20~55℃
	Relative Humidity	15%～93% in operation ≤93% in storage	≤80% in operation ≤93% in storage
	Atmosphere pressure	86kPa～106kPa	86kPa～106kPa
	Low Power Beep Tip Function	No	Yes
	Automatically powered on	Yes	No
Comparison Statement		**The applicant device has similar device specifications as the predicate device**	
Construction	Battery Cover	ABS	ABS

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

Materials	Fingertip Cushion	Laser etching medical silicone gel	Black Medical Silicon gel
	Enclose	ABS	ABS
Comparison Statement		**The materials used in the applicant device are similar as the predicated device except for the material used in the fingertip cushion. The test report was presented in *Biocompatibility*.**	
Performance Testing	Bench Test	The bench tests include Pulse Rate and SpO2 accuracy test after 3000 cycles disinfection, Weak Perfusion Test, High and Low Temperature & Humidity Test and ISO80601-2-61.	Meet the requirements of FDA Guidance
	Clinical Test	Conformed to ISO 80601-2-61	Conformed to ISO 80601-2-61
		Clinical test for device accuracy is conducted by the Yue Bei People's hospital. The clinical test report and protocol are provided in ***Performance Testing-Clinical***	
Electromagnetic compatibility and safety	Electrical Safety	Conformed to IEC60601-1	Conformed to IEC60601-1
	Electromagnetic Compatibility	Conformed to IEC60601-1-2	Conformed to IEC60601-1-2
Software		Moderate Level of Concern	Moderate Level of Concern

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

		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 ISO:14971:2007		Risk Management in Compliance with ISO:14971:2007	
Biocompatibility	Medical Silicon gel	In Vitro Cytotoxicity	No cytotoxic potential.	In Vitro Cytotoxicity	No cytotoxic potential.
		Skin Irritation Test	No evidence of causing sensitization.	Skin Irritation Test	No evidence of causing sensitization.
		Animal Skin Sensitization Test	No evidence of significant sensitization from the test extract to rabbits.	Animal Skin Sensitization Test	No evidence of significant sensitization from the test extract to rabbits.
	ABS plastic Enclosure	In Vitro Cytotoxicity	No cytotoxic potential.	In Vitro Cytotoxicity	No cytotoxic potential.
		Skin Irritation Test	No evidence of causing sensitization.	Skin Irritation Test	No evidence of causing sensitization.
		Animal Skin Sensitization Test	No evidence of significant sensitization from the test extract to rabbits.	Animal Skin Sensitization Test	No evidence of significant sensitization from the test extract to rabbits.
Label and Labeling		Compliance with FDA guidance		Compliance with FDA guidance	

3.6 Intended use

The MD300CL37 Fingertip pulse oximeter 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 patients in hospitals, hospital-type facilities, and home environments.

3.7 Test

Non-clinical Test

The Fingertip Pulse Oximeter MD300CL37 is designed and tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

IEC 60601-1:2005 Medical Electrical Equipment-Part 1: General requirements for safety.

IEC60601-1-2:2007 Medical Electrical Equipment-Part 1-2:General requirements for safety, Collateral standard: Electromagnetic compatibility -Requirements and tests.

IEC60601-1-11:2010 Medical electrical equipment-Part1-11: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.

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

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 compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. The Biological Evaluation Tests are in compliance with the standards of ISO 10993, “Biological Evaluation of Medical Devices”.

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

No.	Test Name
1	Broad-band Vibration Test(The test result is presented in the test report of ISO80601-2-61)
2	Pulse rate and SpO2 Accuracy Test after 3000 cycles’ disinfection
3	System Performance Test
4	Shelf Life Test

5	Performance Test according to ISO 80601-2-61
6	Electromagnetic Compatibility Test According to IEC 60601-1-2
7	Electrical Safety Test According to IEC 60601-1
8	Irritation ,Sensitization and Cytotoxicity Test according to ISO 10993
9	Used in the Home Healthcare Environment Test According to IEC60601-1-11

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

Clinical Test

The Clinical Test reports was conducted in accordance to EN ISO 14155-1:2009, EN ISO 14155-2:2009, ISO 9919:2005, EN ISO 9919:2009, BS EN ISO 80601-2-61:2011, and the FDA Guidance Document for Pulse Oximeters.

Subjects:

After Institutional Review Board (IRB) approval, 12 healthy adult volunteer subjects (ages 21-33yr, 46-75kg, 158-183cm, with light to dark pigmentation) where included in the study conducted July.5-6, 2013 to evaluate the SpO2 accuracy performance of the MD300CL37 Finger Pulse Oximeter.

Methods:

Each system was evaluated during steady state/non-motion conditions with various levels of induced hypoxia resulting in stable oxygen saturation levels between 100% and 70% SaO2. Arterial blood samples were drawn during simultaneous data collection from the test devices. The blood was immediately analyzed on Reference CO-Oximetry providing functional SaO2 for the basis of the SpO2 accuracy comparison.

Adverse events and complications:

There are no adverse events during the clinical test.

Conclusions:

The results show the MD300CL37 Finger Pulse Oximeter to pass a SpO2 accuracy specification of 3 which Beijing Choice Electronic Tech Co., Ltd. claims during steady state conditions over the range of 70-100%.

3.8 Determination of substantial equivalence

The proposed device of Fingertip Pulse Oximeter MD300CL37 has the same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance performance effectiveness, performance

safety as the predicated device. The differences only exist audible indicator and low power beep tip function. These differences are slight and do not influence the effectiveness and safety of the device. According to the non-clinical and clinical test results, the proposed device is as safe as effective and perform as well as the predicate device. So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.