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

April 18, 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, China 100041

Re: K152563
Trade/Device Name: Pulse Oximeter (MD300M, MD300K2)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 7, 2016
Received: March 11, 2016

Dear Mr. 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

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152563

Device Name
Pulse Oximeter

Indications for Use *(Describe)*
The Pulse Oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult, adolescent, child and infant patients in hospitals and clinics.

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.

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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.

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 4104,No.A12 Yuquan Road Haidian District
  100143 Beijing, P.R.China
- **Contact Person:**
  Mr. Lei Chen
  Beijing Choice Electronic Technology Co., Ltd.
  North Building 3F, No. 9 Shuangyuan Road,
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  Email: cc@choicemmed.com
- **Date prepared：March 17, 2016**

3.2 Proposed Device Information

Device Common Name: Pulse Oximeter
Device Trade/Proprietary Name: Pulse Oximeter
Model: MD300M, MD300K2
Classification Name: Oximeter
Regulation Number: 870.2700
Product Code: DQA

Class: Ⅱ

Panel: Anesthesiology

3.3 Predicate Device

510(k) Number: K090599

Common Name: Pulse Oximeter
Device Trade/Proprietary Name: Pulse Oximeter
Model: MD300K1
Classification Name: Oximeter
Product Code: DQA
Regulation Number: 870.2700

Device Class: Ⅱ

Panel: Anesthesiology
Manufacturer: Beijing Choice Electronic Technology Co., Ltd.
Intended Use: MD300K1 Pulse Oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult and pediatric patients in hospitals and home care.

3.4Device Description

The Pulse Oximeter MD300M/MD300K2 can display the SpO2%, pulse rate, Pulse Amplitude Index and other indication parameters, such as time, ID number, pulse amplitude bar and battery power status, alarm limits and the connections of sensors. It is used for adult, adolescent, child and infant patients. The device has physiological alarm and technology alarm function. There are two-level alarm priorities in oximeter. High priority: “Di-Di-Di-------Di—Di” indicates the patient is in the very dangerous situation. Low priority: “Di” indicates the technical alarm caused by the device itself. The device also has visual alarm function to indicate users by lamp and information on the device. The power supply of the applicant device is 3 AA alkaline batteries, rechargeable batteries or adapter.

The proposed device consists of photo detector, display screen, signal amplify unit, CPU, display unit and power supply unit.

Principle of the oximeter is as follows: A mathematic formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in red and near-infrared zones. Operation principle of the instrument: Photoeletric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 905nm near infrared light) can be focused on 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.

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***.

3.5 Comparison list of the technological characteristics

Table 3-1 Performance Specification Comparison Table between the Proposed Device (MD300M) and Predicate Device

Comparison Elements	**Proposed Device**	**Predicate Device**
Product Name	Pulse Oximeter	Pulse Oximeter
Model	MD300M	MD300K1
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 MD300M pulse oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult, adolescent, child and infant patients in hospitals and clinics.	MD300K1 Pulse Oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult and pediatric patients in hospitals and home care.
Comparison Statement	**The proposed device and the predicated device have the similar intended use and classification. The only difference is that the proposed device cannot be used in the home care environment while the predicated device can be used in the home care environment.**	
Components	Photo detector, display screen, signal amplify unit, CPU, display unit and power unit.	Photo detector, display screen, signal amplify unit, CPU, display unit and power unit.
Design Principle	Principle of the oximeter is as follows: A mathematic formula is established making use	The MD300K1 Pulse Oximeter works by applying a sensor to a pulsating arteriolar

		of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in red and near-infrared zones. Operation principle of the instrument: Photoeletric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 905nm near infrared light) can be focused on 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.	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 normally absorb a constant amount 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 nanometers
	Infrared	905±8nm	940 nanometers
Comparison Statement		**The proposed device and the predicate device have the same design principle and similar measurement wavelength.**	
	Display Type	TFT (colorized)	OLED
	Battery	3*AA alkaline batteries, rechargeable batteries or adapter	2*AA alkaline batteries

Performance Specification	Power adapter	5V 2A	Not available
	SpO2 display range	0%~100%	0~100%
	SpO2 measurement range	0~100%	0~100%
	SpO2 accuracy	70%~100%, ±2%; 0~69% no definition	70%~100%, ±3%; 0~69% no definition
	PR display range	0~250bpm	0~235bpm
	PR measurement range	30~250bpm	30~235bpm
	PR accuracy	30bpm~99bpm, ±2bpm 100bpm~250bpm, ±2%	30bpm~99bpm, ±2bpm 100bpm~235bpm, ±2%
	PR Resolution	1%	1%
	Pulse amplitude index measurement range	0.1%~20%	---
	Operating temperature	0℃~40℃	5℃~40℃
	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

	Alarm type		Audio type, visual alarm and information	Audio type, visual alarm and information
	Alarm limit range		SpO2 70%~100% PR 30bpm~250bpm	SpO2 70%~100% PR 30bpm~235bpm
	Default Limit	SpO2	High 100%, Low 90%	High 99%, Low 90%
		PR	High 100bpm, Low 60bpm	High 100bpm, Low 60bpm
Comparison Statement			**The proposed device has similar product specification as predicate device.**	
Contacting Material	Battery Cover		ABS	ABS
	Plastic Case Cover			
	Fingertip Cushion		Medical Silicone Gel (Finger probe M-50E012CS09, M-50B008CS09)	Medical Silicone Gel (Finger probe M-50 series)
	Fingertip Cushion		Microfoam (Finger probe M-50J033CS045)	N/A
Comparison Statement			**The contacting materials of the proposed device are similar to those of the predicate device. The only difference is that the material of MD300M supporting finger probe** M-50J033CS045 **is microfoam while which is not available to 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
	Clinical Testing		Conformed to ISO9919&ISO 80601-2-61	Conformed to ISO9919

		Clinical Test for the device accuracy is conducted in Yue Bei people's Hospital. The clinical test report and protocol are provided in Performance Testing-Clinical Test Report		
EMC and Electrical Safety	Electrical Safety	Conformed to IEC60601-1, IEC 60601-1-8		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
		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
Biocompati	Microfoam	In Vitro Cytotoxicity	No cytotoxic potential	N/A

		Animal skin irritation test	No evidence of significant irritation from the test extract to rabbits	
		Skin Sensitization Test	No evidence of sensitization was observed.	
Comparison Statement		**Compliance with ISO10993**		
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 (MD300K2) and Predicate Device

Comparison Elements	**Proposed Device**	**Predicate Device**
Product Name	Pulse Oximeter	Pulse Oximeter
Model	MD300K2	MD300K1
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 MD300K2 pulse oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult, adolescent, child and infant patients in hospitals and clinics.	MD300K1 Pulse Oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult and pediatric patients in hospitals and home care.

Comparison Statement		**The proposed device and the predicated device have the similar intended use and classification. The only difference is that the proposed device cannot be used in the home care environment while the predicated device can be used in the home care environment.**	
Components		Photo detector, display screen, signal amplify unit, CPU, display unit and power unit.	Photo detector, display screen, signal amplify unit, CPU, display unit and power unit.
Design Principle		Principle of the oximeter is as follows: A mathematic formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in red and near-infrared zones. Operation principle of the instrument: Photoeletric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 905nm near infrared light) can be focused on 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.	The MD300K1 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 normally absorb a constant amount 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 nm
	Infrared	905±10nm	940 nm

Comparison Statement		**The proposed device and the predicate device have the same design principle and similar measurement wavelength.**	
	Display Type	TFT (colorized)	OLED
	Battery	3*AA alkaline batteries, rechargeable batteries or adapter	2*AA alkaline batteries
Performance Specification	Power adapter	5V 2A	Not available
	SpO2 Display Range	0~100%	0~100%
	SpO2 Measurement Range	0~100%	0~100%
	SpO2 Accuracy	70%~100%, ±2%; 0~69% no definition	70%~100%, ±3%; 0~69% no definition
	SpO2 resolution	1%	1%
	PR Display Range	0~250bpm	0~235bpm
	PR Measurement Range	30bpm~250bpm	30bpm~235bpm
	PR Accuracy	30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%	30bpm~99bpm, ±2bpm; 100bpm~235bpm, ±2%
	PR Resolution	1%	1%
	Pulse amplitude index display range	0.1%~20%	---

	Operating Temperature		0℃~40℃	5℃~40℃
	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
	Alarm type		Audio type, visual alarm and information	Audio type, visual alarm and information
	Alarm limit range		SpO2 70%~100% PR 30bpm~250bpm	SpO2 70%~100% PR 30bpm~235bpm
	Default Limits	SpO2	High 100%, Low 95%	High 99%, Low 90%
		PR	High 100bpm, Low 60bpm	High 100bpm, Low 60bpm
Comparison Statement			**The proposed device has similar product specification as predicate device.**	
Contacting Material	Battery Cover		ABS	ABS
	Plastic Case Cover			
	Fingertip Cushion		Medical Silicone Gel(Finger probe M-50E012CS09, M-50B008CS09)	Medical Silicone Gel(M-50 series)
	Fingertip Cushion		Microfoam(Finger probe M-50J033CS045)	N/A
Comparison Statement			**The contacting materials of the proposed device are similar to those of the predicate device. The only difference is that the material of MD300K2 supporting finger probe** M-50J033CS045 **is microfoam while which is not available to 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 60601-1-8		Conformed to IEC60601-1
EMC and Electrical Safe	Electromagnetic Compatibility	Conformed to IEC60601-1-2		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
Biocompatibility	Microfoam	In Vitro Cytotoxicity	No cytotoxic potential	N/A
		Animal skin irritation test	No evidence of significant irritation from the test extract to rabbits	

		Skin Sensitization Test	No evidence of sensitization was observed.	
Comparison Statement		**Compliance with ISO10993**		
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 MD300M/MD300K2 pulse oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult, adolescent, child and infant patients in hospitals and clinics.

3.7 Functional and Safety Testing:

Non-Clinical Test

The Pulse Oximeter MD300M/MD300K2 is designed and tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

IEC 60601-1:2005/AC:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2007 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC 60601-1-8:2012 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

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

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 ISO10993. “Biological Evaluation of Medical Devices”.

The list of non-clinical test performed on the proposed device is shown as following:

No.	Test Name
1	System Performance Test
2	Shelf Life Test
3	Performance Test after Cleaning
4	Performance Test according to ISO 80601-2-61
5	Electromagnetic Compatibility Test According to IEC 60601-1-2
6	Electrical Safety Test According to IEC 60601-1

7	Alarm System Tests According to IEC60601-1-8
8	Irritation ,Sensitization and Cytotoxicity Test according to ISO 10993

Clinical Test

The Clinical Test 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 supporting Oximeter probes of Pulse Oximeter MD300M are adult finger probe M-50E012CS09, pediatric finger probe M-50B008CS09, single use probe M-50J033CS045. The clinical study of MD300M was conducted with its supporting finger probe respectively.

The Clinical Test of MD300M was conducted in Yue Bei people's Hospital. The clinical s study report was presented in ***Performance Testing-Clinical Test Report***.

Subjects information:

12 healthy adult volunteer subjects (6 females and 6 males ages 21-43yr, 47-82kg, 155-185cm, among which 6 with light pigmentation from Asian, 3 with light (white) pigmentation from Caucasian, 3 with dark pigmentation from African) were included in the study connected Sep. 20-22, 2014 to evaluate the SpO2 accuracy performance of the MD300M Pulse Oximeter and its supporting M-50E012CS09/M-50B008CS09/ M-50J033CS045 Oximeter Probe.

Results:

The SpO2 accuracy performance results showed the MD300M Pulse Oximeter and its supporting M-50E012CS09 Oximeter probe to have an Arms of 1.75 during steady state conditions over the range of 70-100%.

The SpO2 accuracy performance results showed the MD300M Pulse Oximeter and its supporting M-50B008CS09 Oximeter probe to have an Arms of 1.48 during steady state conditions over the range of 70-100%.

The SpO2 accuracy performance results showed the MD300M Pulse Oximeter and its supporting M-50J033CS045 Oximeter probe to have an Arms of 1.75 during steady state conditions over the range of 70-100%.

Conclusion:

The results of the study provide supporting evidence that the pulse oximeter MD300M with its supporting finger probes was compliance to the accuracy specification claimed by the manufacturer.

The proposed device MD300K2 and MD300M have similar hardware and software design. They have same contain identical materials, electro-optical component, SpO2 module,

same supporting finger probes and have equivalent sensor characteristics. The main difference between them is the appearance design (enclosure). So we think MD300M clinical study results can be to support clearance of the proposed device of MD300K2.

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

3.8 Determination of substantial equivalence

The proposed device of Pulse Oximeter MD300M/MD300K2 has the same classification information, similar intended use, same design principle, similar product design and specifications as the predicated device. The differences exist in display screen, SpO2 accuracy and PR display range. The main difference is that the proposed device cannot be used in the homecare environment while the predicated device can be used in the home care environment. The differences are slight and do not influence the effectiveness and safety of the device. According to the laboratory and clinical 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.