March 16, 2018

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

Re: K172366
Trade/Device Name: Wrist Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: February 12, 2018
Received: February 14, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang
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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): K172366

Device Name: Wrist Pulse Oximeter

Indications for Use:

MD300W512 / MD300W314/ MD300W314B4 is a wrist pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, adolescent, child and infant patients. It is intended for spot-check and / or data collection, recording and transmitting. It can be used in sleep labs, long-term care, hospitals and home use.

Prescription Use √	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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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.

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:**
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  Fax:215-4052545
  Email: cc@choicemmed.com
- **Date prepared：February 12, 2018**

3.2 Proposed Device Information

Device Common Name: Wrist Pulse Oximeter
Device Trade/Proprietary Name: Pulse Oximeter
Model: MD300W512/MD300W314/MD300W314B4
Classification Name: Oximeter
Regulation Number: 870.2700
Product Code: DQA

Class: Ⅱ

Panel: Anesthesiology

3.3Predicate Device

510(k) Number: K081125
Common Name: Wrist Pulse Oximeter
Device Trade/Proprietary Name: Pulse Oximeter
Model: MD300W
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 MD300W wrist oximeter is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate adult and pediatric patient at home, and hospital (including clinical use in internist/ surgery, Anesthesia, intensive care and etc). Not for continuously monitoring.

3.4Device Description

The proposed devices Wrist Pulse Oximeter MD300W512 /MD300W314/MD300W314B4 are internally powered devices. The main functions of the devices include hemoglobin oxygen saturation (SpO2) and pulse rate (PR) measurements, visual and audible indication, data storage and transmission.

The proposed device MD300W512/MD300W314/MD300W314B4 consists of power supply module, detector and emitter LED, signal collection and process module, display module, user interface, button control circuit, data storage and transmission module.

The proposed devices Wrist Pulse Oximeter MD300W512/MD300W314/MD300W314B4 share the same measurement principle, appearance, 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

	MD300W512	MD300W314	MD300W314B4
Display Screen Type	OLED	LCD	OLED
Power Supply	2 AAA alkaline batteries	Lithium-ion rechargeable battery	Lithium-ion rechargeable battery

Data transmission	By USB cable	By Bluetooth or USB cable	By Bluetooth
Bluetooth module	No	2.0	4.0

The device is not for life-supporting or life-sustaining, not for implant. The device or sensor is not sterile and the sensor does not need sterilization and the sensor is reusable but does not need re-sterilization since it is not sterile. 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 (MD300W512) and Predicate Device

Parameter	**Proposed Device**	**Predicate Device**
Product Name	Wrist Pulse Oximeter	Wrist Pulse Oximeter
Model	MD300W512/MD300W314/MD300W314B4	MD300W
Regulation No.	21 CFR 870.2700	21 CFR 870.2700
Classification	II	II
Classification Name	Oximeter	Oximeter
Product Code	DQA	DQA
Indications for use	MD300W512 / MD300W314/ MD300W314B4 is a wrist pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, adolescent, child and infant patients. It is intended for spot-check and / or data collection, recording and transmitting. It can be used in sleep labs, long-term care, hospitals and home use.	The MD300W wrist oximeter is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate adult and pediatric patient at home, and hospital (including clinical use in internist/ surgery, Anesthesia, intensive care and etc). Not for continuously monitoring.
Comparison Statement	The proposed device and the predicate device have the same intended use and classification. The minor	

		differences in the indication statements do not raise different questions of safety or effectiveness.	
Components		The proposed devices consist of power supply module, detector and emitter LED, signal collection and process module, display module, user interface, button control circuit, data storage and transmission module.	The predicate device consists of sensor, signal amplify unit, CPU, data display unit, data transmit unit, storage 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 absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.	The wrist oximeter works by applying a sensor to a pulsating arterial 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 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±2nm
	Infrared	905±10nm	940±10nm

Comparison Statement		The proposed device and the predicate device have the same design principle and similar measurement wavelength.		
Performance Specification	Display Type	MD300W512/MD300W314B4	OLED	LCD
		MD300W314	LCD	
	Power Supply	MD300W512	2 AAA alkaline batteries	One AAA alkaline battery
		MD300W314/MD300W314B4	Lithium rechargeable batteries	
	SpO2 measurement range	70%~100%		70%~100%
	SpO2 accuracy	70%~100%, ±2%; <70%: unspecified		70%~100%, ±3%; <70%: unspecified
	PR display range	30-255bpm		0~254bpm
	PR measurement range	30-250bpm		30~235bpm
	PR accuracy	30-99bpm, ±2bpm; 100~250bpm, ±2%		30-99bpm, ±2bpm; 100~250bpm, ±2%
	PR Resolution	1bpm		1bpm
	Operating temperature	5~40℃		5~40℃
	Storage and transportation environment	-25~70℃		-20~70℃
	Relative humidity	≤93%, no condensation		≤93%, no condensation

	Atmosphere pressure	70kPa~106kPa		86kPa~106kPa
	Dimensions (L x W x H)	MD300W512	70mm x 67mm x 30mm	50mm x 60mm x20mm
		MD300W314	67mm x 66mm x 28mm	
		MD300W314B4	67mm x 66mm x 28mm	
Bluetooth Technology		MD300W512	Not apply	Not apply
		MD300W314	Bluetooth 2.0 Module	
		MD300W314B4	Bluetooth 4.0 Module	
Comparison Statement		The proposed device has similar product specification as the predicate device.		
Contacting components	Fingertip Cushion	Medical Silicone (Oximeter probe M-50G010CS03)		Medical Silicone
	Wrist Belt	Nylon brand		Nylon brand
	Plastic Case Cover	ABS		ABS
Contacting Duration	Fingertip Cushion	Less than 24h		Less than 24h
	Wrist Belt			
	Plastic Case Cover	Patient rarely contacted		Patient rarely contacted
Type of contact	Fingertip Cushion	Skin surface-contacting		Skin surface-contacting
	Wrist Belt			
	Plastic Case Cover			

Comparison Statement		**The contacting materials of the proposed device are similar 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		The laboratory tests include SpO2 and PR accuracy Test, Weak Perfusion Test, High and Low Temperature and Humidity Test, Performance Test After Cleaning and ISO9919	
	Clinical Testing	Conformed to ISO 80601-2-61. 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		Conformed to ISO9919	
EMC and Electrical Safety	Electrical Safety	Conformed to IEC60601-1, IEC60601-1-11		Conformed to IEC60601-1	
	Electromagnetic Compatibility	Conformed to IEC60601-1-2		Conformed to IEC60601-1-2	
Biocompatibility	Biocompatibility Test Report	In Vitro Cytotoxicity	No cytotoxic potential	In Vitro Cytotoxicity	Grade I
		Animal skin irritation test	No evidence of significant irritation from the test extract to rabbits	Skin Irritation Test	Primary Irritation Index(PII)was 0.0
		Skin Sensitization Test	No evidence of sensitization was observed.	Skin Sensitization Test	No Evidence of delayed dermal contact sensitization
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

MD300W512 / MD300W314/ MD300W314B4 is a wrist pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, adolescent, child and infant patients. It is intended for spot-check and / or data collection, recording and transmitting. It can be used in sleep labs, long-term care, hospitals and home use.

3.7 Functional and Electrical Safety Testing:

Non-clinical Test:
The Wrist pulse oximeter 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 60601-1-2:2014 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 medical 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.

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	Medical electrical equipment and medical electrical system used in the home healthcare environment according to IEC 60601-1-11
8	Irritation ,Sensitization and Cytotoxicity Test according to ISO 10993

Clinical Test

The Clinical study of MD300W512 Wrist Pulse Oximeter and its supporting M-50G010CS03 Oximeter probe was conducted in accordance to ISO 14155-1, -2, 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 21-43yr, 47-82kg, 155-185cm, with light to dark pigmentation) were included in the study conducted Sep. 20-22, 2014 to evaluate the SpO2 accuracy performance of the MD300W512 Wrist Pulse Oximeter and its supporting M-50G010CS03 Oximeter probe.

Method:

Each system was evaluated during steady state/ non-motion conditions with various levels 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.

Conclusion:

The SpO2 accuracy performance results showed the MD300W512 Wrist Pulse Oximeter and its supporting M-50G010CS03 Oximeter probe to have an ARMS of 1.71 during steady state conditions over the range of 70-100%. The results show the MD300W512 Wrist Pulse Oximeter and its supporting M-50G010CS03 Oximeter probe is compliance to the accuracy specification claimed by the manufacturer.

The proposed device MD300W314/MD300W314B4 and the device MD300W512 have the same electro-optical component, SpO2 module and have equivalent sensor characteristics. So we think the predicate device clinical study results can be as the clinical study results of the proposed device.

3.8 Determination of substantial equivalence

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