JUL 17 2014

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 K140682

3.1 Date of Submission: June 11, 2014

3.2 Sponsor Information

Establishment Registration Number: 3005569927
Beijing Choice Electronic Technology Co., Ltd.
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Contact Person:
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3.3 Proposed Device Information

Device Common or Usual Name: Pulse Oximeter
Device Trade or Proprietary Name: Fingertip Pulse Oximeter
Model: MD300C29-H
Classification Name: Oximeter
Product Code: DQA
Regulation Number: 870.2700
Panel: Anesthesiology
Class: II

3.4 Predicate Device

510(k) Number: K070371
Common Name: Oximeter
Device Trade or Proprietary Name: Fingertip Pulse Oximeter
Model: MD300C
Classification Name: Oximeter

Device Class: II
Product Code: DQA
Regulation Number: 870.2700
Review Panel: Anesthesiology
Manufacturer: Beijing Choice Electronic Technology Co., Ltd.
Intended Use: Fingertip Pulse Oximeter MD300C is a portable non-invasive, spot-check, 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 and etc). Not for continuously monitoring.

3.5 Device Description

The proposed device Fingertip Pulse Oximeter MD300C29-H is a battery powered device, which can detect and display the measured %SpO_2 and pulse rate value, pulse bar graph and SpO_2 waveform. The device is normally applied to adult, child and adolescent patient in the hospital.

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.

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 SpO_2.

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 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 ***Software***

3.6 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.

3.7 Comparison with the Predicate Device

Comparison Elements	Applicant Device	Predicate Device
Device Name	Fingertip Pulse Oximeter MD300C29-H	MD300C Fingertip Pulse Oximeter (K070371)
Model	MD300C29-H	MD300C
Regulation No.	21 CFR 870.2700	21 CFR 870.2700
Classification	II	II
Classification Name	Oximeter	Oximeter
Product Code	DQA	DQA
Indented 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, child and adolescent patient in hospital.	Fingertip Pulse Oximeter MD300C is a portable non-invasive, spot-check, 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 and etc). Not for continuously monitoring.
Comparison Statement	**The proposed devices have the similar intended use and classification.**	
Components	The applicant device consists of 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	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.	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.

Measurement wavelength	Red	660±3nm	660±2nm
	Infrared	905±8nm	940±10nm
Comparison Statement		**The proposed device has the same design principle and similar components. The only difference is the wavelength of the infrared LED emitter, and we can verify that which will not effect the basic safety and the essential performance of the proposed device.**	
Device Specification	Display Type	OLED	OLED
	Working time	Approximately 25 hours of continuous operation	Approximately 30 hours of continuous operation
	Brightness of backlight	Adjustable	Adjustable
	User Interface	6 directions for display	6 directions for display
	Power supply	2*AAA alkaline battery	2*AAA alkaline battery
	Display Data	SpO_2; PR	SpO_2, PR
	SpO_2 display range	35%~100%	0~100%
	SpO2 measurement range	70~100%	70~100%
	SpO_2 Accuracy	70%~100%; ±2% 0%~69% no definition	70%~100%; ±3% 0%~69% no definition
	SpO_2 resolution	1%	1%
	PR Display Range	30-250bpm	0-254bpm
	PR Measurement Range	30~250bpm	30~235bpm
	PR Accuracy	±2bpm（30-99bpm）and ±2%（100-250bpm）	±2bpm（30-99bpm）and ±2%（100-235bpm）
	PR resolution	1bpm	1bpm
	Operating temperature	5℃~40℃	5℃~40℃
	Relative humidity	≤80% ， no condensation (operating) ≤93% no condensation (storage)	≤80% ， no condensation (operating) ≤93% no condensation (storage)
	Atmosphere pressure	86kPa~106kPa	86kPa~106kPa
Comparison Statement		**The proposed device has similar device specifications as the predicate device.**	

Contacting Material	Battery cover	ABS	ABS
	Enclosure		
	Fingertip Cushion	Laser Etching Medical Silicon gel	Medical Silicon gel
	Power button		
	Coating	Inks	Inks
Comparison Statement		**The contacting materials of Proposed device are same to those of the predicate device except Fingertip Cushion and Power Button.**	
Performance Testing	Bench Test	The bench tests include SpO2 and PR accuracy Test, Weak Perfusion Test, High and Low Temperature and Humidity Test, Performance Test After Disinfection and ISO 80601-2-61.	Meet the requirements of FDA Guidance
	Clinical Test	Conformed to ISO 9919 & ISO80601-2-61	Conformed to ISO 9919
		Clinical test for device accuracy is conducted in the Yue Bei people's Hospital. The clinical test report and protocol are provided in Performance Testing - Clinical Test Report.	
EMC and Electrical Safe	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
		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	Medical silicone 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 irritation test	No evidence of significant irritation from the test extract to rabbits	Animal skin irritation test	No evidence of significant irritation from the test extract to rabbits
Comparison Statement		**Compliance with the ISO 10993**			
Label and Labeling		Compliance with the Guidance of pulse oximeter-premarket notification submission issued on March 4, 2013		Compliance with FDA guidance	

3.8 Test Conclusion

Non-clinical Test

The Fingertip Pulse Oximeter MD300C29-H 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.*

The Software Validation is in 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".

Clinical Test

The Clinical Test were 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 results of the study provide supporting evidence that the Fingertip Pulse Oximeter MD300C29-H is compliance to the accuracy specification claimed by the manufacturer. The Fingertip Pulse Oximeter can be used under steady state / non-motion conditions for the range 70-100%.

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, performance safety as the predicate device. The main difference is the wavelength of the infrared LED emitter, and we can verify that which will not effect the basic safety and the essential performance of the proposed device. So the proposed devices are Substantially Equivalent (SE) to the predicate device which is US legally market device.

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

July 17, 2014

Beijing Choice Electronic Technology Co., Ltd.
Mr. Lei Chen
Quality Director
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Re: K140682
Trade/Device Name: Fingertip Pulse Oximeter MD300C29-H
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 11, 2014
Received: June 16, 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,

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Clinical Deputy Director
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Radiological Health

Enclosure

Section II Indication for Use Statement

Indication for Use

510(k) Number (if known): K140682

Device Name: Fingertip Pulse Oximeter MD300C29-H

Indications for 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.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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