

Section 3 510(k) Summary

(As required by 21 CFR 807.92)

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

There is no prior submission for the devices.

The assigned 510(K) number is K131047

3.1 Date of Submission: Sept. 10, 2013

OCT 16 2013

3.2 Sponsor Information

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, P.R. China, 100041
Phone: +86-10-88798300 Ext 6020
Fax: 215-4052545
Email: cc@choicemmed.com

3.3 Proposed Device Information

Device Common or Usual Name: Pulse Oximeter

Device Trade or Proprietary Name: Fingertip Pulse Oximeter

Model: MD300CB3

Classification Name: Oximeter

Product Code: DQA

Regulation Number: 870.2700

Panel: Anesthesiology

Class: II

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.

Intended Use: 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.

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 applicant device of Fingertip Pulse Oximeter MD300CB3 is a battery powered fingertip device, which can detect and display the measured %SpO₂ and pulse rate value, pulse bar graph and SpO₂ waveform. The device is normally applied to adult, adolescent, child and infant patient in hospital.

The applicant 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 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.

The applicant devices are not for life-supporting or life-sustaining, not for implant. The devices or transducers are not sterile and the transducers are reusable and do not need sterilization or re-sterilization. The devices are for prescription. The devices do not contain drug or biological products.

The devices are software -driven and the software validation is provided in *Software*.

3.6 Intended Use

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.

3.7 Contraindication

The Fingertip Pulse Oximeter MD300CB3 is not for continuous monitoring.

3.8 Comparison with the Predicate Device

Table 3-1 Performance Specification Comparison

Comparison Elements	Proposed Device	Predicate Device
Device Name	Fingertip Pulse Oximeter MD300CB3	MD300C Fingertip Pulse Oximeter (K070371)
Model	MD300CB3	MD300C
Regulation No.	21 CFR 870.2700	21 CFR 870.2700
Classification	II	II
Classification Name	Oximeter	Oximeter
Product Code	DQA	DQA
Intended Use	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.	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 same 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

<p>Design Principle</p>	<p>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.</p>	<p>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.</p>
<p>Measurement wavelength</p>	<p>Red 660 ± 2nm Infrared 940 ± 10nm</p>	<p>660 ± 2nm 940 ± 10nm</p>
<p>The proposed devices have the same design principle and similar components.</p>		
<p>Device Specification</p>		
<p>Display Type</p>	<p>OLED</p>	<p>OLED</p>
<p>Working time</p>	<p>Work for 8 hours continuously</p>	<p>Approximately 30 hours of continuous operation</p>
<p>Brightness of backlight</p>	<p>Adjustable</p>	<p>Adjustable</p>
<p>User Interface</p>	<p>6 directions for display</p>	<p>6 directions for display</p>
<p>Power supply</p>	<p>1* AAA alkaline battery</p>	<p>2* AAA alkaline battery</p>
<p>Display Data</p>	<p>SpO₂, PR</p>	<p>SpO₂, PR</p>
<p>SpO₂ display range</p>	<p>0~100%</p>	<p>0~99%</p>
<p>SpO₂ measurement range</p>	<p>70~100%</p>	<p>70~99%</p>
<p>SpO₂ Arms Accuracy</p>	<p>70%~100%: 1.94; 70%~80%: 2.32; 80%~90%: 1.95; 90%~100%: 1.57; 0%~69% no definition</p>	<p>70%~99%: ±3% 0%~69% no definition</p>

Premarket Notification 510(k) Submission – Sec 3.510(k) Summary

SpO ₂ resolution	1%	1%
PR Display Range	0-254bpm	0-254bpm
PR Measurement Range	30-235bpm	30-235bpm
PR Accuracy	±2bpm (30-99bpm) and 2% (100-235bpm)	±2bpm (30-99bpm) and 2% (100-235bpm)
PR resolution	1bpm	1bpm
Operating temperature	5°C ~40°C	5°C ~40°C
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 applicant device has similar device specifications as the predicate device.		
Contacting Material	Battery cover	Medical Silicon gel
	Fingertip Cushion	Medical Silicon gel
	Enclosure	Medical Silicon gel
Comparison Statement The contacting materials of applicant device are similar to that of the predicate device.		
Performance Testing	Bench Test	The bench tests include Test for Pulse signal strength Indicator Bar, Pulse rate and SpO ₂ accuracy test after 3000 cycles disinfection, Test for Random vibration, wide band and Test according to ISO9919. All the bench test results are provided in <i>Performance Testing-Bench</i>
	Clinical Test	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 <i>Performance Testing-Clinical</i>
		Meet the requirements of FDA Guidance
		Conformed to ISO 9919

Premarket Notification 510(k) Submission – Sec 3.510(k) Summary

	Electrical Safety	<p>Conformed to IEC60601-1.</p> <p>The test results are provided in <i>Electromagnetic Compatibility and Electrical Safety</i></p>	Conformed to IEC60601-1
	Electromagnetic Compatibility	<p>Conformed to IEC60601-1-2.</p> <p>The EMC test reports were provided in <i>Electromagnetic Compatibility and Electrical Safety</i></p>	Conformed to IEC60601-1-2.
Biocompatibility	Medical silicone gel	<p>Moderate Level of Concern</p> <p>Compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.</p>	Moderate Level of Concern
		<p>Risk Management in Compliance with IEC 60601-1-4</p>	<p>Risk Management in Compliance with IEC 60601-1-4</p>
		<p>In Vitro Cytotoxicity</p> <p>Skin Irritation Test</p> <p>Animal skin irritation test</p>	<p>No cytotoxic potential</p> <p>No evidence of causing sensitization</p> <p>No evidence of significant irritation from the test extract to rabbits</p>
	Label and Labeling	<p>Compliance with the Guidance of pulse oximeter-premarket notification submission issued on March 4, 2013</p>	Compliance with FDA guidance

3.9 Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:1988 + A1(1991) + A2(1995), 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 9919:2005, Medical electrical equipment - Particular requirements for basic safety and essential performance of pulse oximeter equipment for medical use.

ISO10993-5: 2009, Biological evaluation of medical device – Part 5: Tests for in vitro cytotoxicity.

ISO10993-10: 2010, Biological evaluation of medical device – Part 10: Tests for irritation and delayed-type hypersensitivity.

The Clinical Test of MD300CB3 following ISO 9919:2005, Annex EE.4 was conducted in Yue Bei people's Hospital. The study protocol was subjected to ISO 9919:2005 Annex EE. Procedures of testing required in EE2 were adopted. It can be determined from the result of the study that the accuracy of the proposed device is compliance to the specification claimed by the manufacturer compared with "Golden Standard" Co-Oximeter.

3.9 Substantially Equivalent Conclusion

The proposed device, Fingertip Pulse Oximeter MD300CB3, is determined to be Substantially Equivalent (SE) to the predicate device, Fingertip Pulse Oximeter MD300C, K070371, in respect of safety and effectiveness.



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

October 16, 2013

Beijing Choice Electronic Technology Co., Ltd
Mr. Lei Chen
3270 Alpine Road
North Building 3F, No.9 Shuangyuan Road,
Badachu Hi-tech Zone, Shijingshan District,
Beijing, P.R. China, 100041

Re: K131047

Trade/Device Name: Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 13, 2013
Received: September 16, 2013

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" (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 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,



Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer, M.S.
Acting Director
Division of Anesthesiology,
Respiratory, General Hospital, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indications for Use Statement

Indications for Use

510(k) Number (if known): K131047

Device Name: Fingertip Pulse Oximeter MD300CB3

Indications for Use:

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.

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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Page 1 of 1