K123871

MAY 10 2013

Section 3 510(k) Summary

(As required by 21 CFR 807.92)

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

The assigned 510(k) Number is: Pending

3.1 Date of Submission: Dec. 14, 2012

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
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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: MD300CF315
Classification Name: Oximeter
Product Code: DQA
Regulation Number: 870.2700
Panel: Anesthesiology

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.

3.5 Device Description

The applicant device of Fingertip Pulse Oximeter MD300CF315 is a battery powered fingertip device, which can detect, display and speak out the measured %SpO_2 and pulse rate value. The device is normally applied to adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care etc).

The applicant device consists of power supply module, detector and emitter LED, signal collection and process module, display module, user interface, voice module 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 SpO_2.

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 Section 11 Software.

3.6 Intended Use

The Fingertip Pulse Oximeter MD300CF315 is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care etc). It is not for continuous monitoring.

3.7 Comparison with the Predicate Device

Table 3-1 Performance Specification Comparison

ITEM		Proposed Device	Predicate Device
Product Name		MD300CF315 Fingertip Pulse Oximeter	MD300C Fingertip Pulse Oximeter
Power		2 AAA-size alkaline batteries	2 AAA-size alkaline batteries
Low Power Beep Tip Function		Yes	No
Display Part		OLED	OLED
User Interface		4 directions for display	6 directions for display
SpO_2	Display Range	0～99%	0～99%
	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	0～254BPM	0～254BPM
	Measurement Range	30～235BPM	30～235BPM
	Accuracy	30 ～ 99bpm, ±2bpm; 100 ～ 235bpm, ±2%	30～99bpm, ±2bpm; 100～235bpm, ±2%
	Resolution	1bpm	1bpm
Sensor LED Wavelength	RED	660±2nm	660±2nm
	IR	940±10nm	940±10nm
Environment Requirements	Operation Temperature	5～40℃	5～40℃
	Storage Temperature	-20～55℃	-20～55℃
	Operation Relative Humidity	≤80%, no condensation	≤80%, no condensation
	Storage Relative Humidity	≤93%, no condensation	≤93%, no condensation

Construction Materials		1. ABS plastic 2. Medical silicone gel	1. ABS plastic 2. Medical silicone gel
Outline product	Dimension	60mm×36mm×39mm (L×W×H)	58mm×32mm×34mm (L×W×H)
	Weight	46g	32g

Table 3-2 Differences between the Proposed Device and Predicate Device

ITEM	Proposed Device		Predicate Device
Device Name	Fingertip Pulse Oximeter MD300CF315		Fingertip Pulse Oximeter MD300C（K070371）
Components	Power supply module, detector and emitter LED, signal collection and process module, display module, user interface, voice module and button control circuit		Power supply module, detector and emitter LED, signal collection and process module, display module, user interface and button control circuit
Low Power Beep Tip Function	Yes		No
User Interface	4 directions for display		6 directions for display
Outline product	Dimension	60mm×36mm×39mm (L×W×H)	58mm×32mm×34mm (L×W×H)
	Weight	46g	32g

3.8 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 Fingertip Pulse Oximeter MD300CF315 share the same Blood Oxygen Module with the predicate device MD300C, so we believe the clinical test of MD300CF315 can be exempted.

3.9 Substantially Equivalent Conclusion

The proposed device, Fingertip Pulse Oximeter MD300CF315, is determined to be Substantially Equivalent (SE) to the predicate device, Fingertip Pulse Oximeter MD300C, K070371, in respect of safety and effectiveness.

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

May 10, 2013

Mr. Lei Chen
Beijing Choice Electronic Technology Company, Limited
North Building 3F, No.9 Shuangyuan Road
Badachu Hitech, Shijingshan District
Beijing, China 100041

Re: K123871
Trade/Device Name: Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 10, 2013
Received: April 12, 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Kwame O. Ulmer for
-S FDA

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indications for Use

Indications for Use Form

510(k) Number (if known): K123871

Device Name: Fingertip Pulse Oximeter

Indications for Use:

The Fingertip Pulse Oximeter MD300CF315 is a portable, non-invasive device intended for spot checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care etc). It is not for continuous monitoring.

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)

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Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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