Attachment VI 510(k) Summary

DEC 2 2010

(As required by 21 CFR 807.92)

1. Date Prepared: May 26, 2010

2. Statement

This is a special 510(k) report for Fingertip Pulse Oximeters MD300C series, which are modification devices to Fingertip Pulse Oximeter MD300C (K070371). The modification does not change intended use or trade name. The main modifications are listed below:

Model	Difference to MD300C
MD300C3	1. PCB layout 2. Add a speaker, pulse beep and sound tips 3. The shape and size of shell
MD300CF3	1. PCB layout 2. Add a speaker, pulse beep and sound tips 3. The shape and size of shell
MD300C310	1. PCB layout 2. Add a speaker, pulse beep and sound tips 3. The shape and size of shell 4. The screen: MD300C310 is coloured OLED, MD300C is double-colour OLED
MD300C9111	1. The screen: MD300C9111 is LED digital tube, MD300C is double-colour OLED. 2. PCB layout 3. Add a USB port for an external probe connected. 4. The shape and size of shell
MD300C9211	1. The screen: MD300C9211 is coloured OLED, MD300C is double-colour OLED. 2. PCB layout 3. Add a USB port for an external probe connected. 4. The shape and size of shell

MD300C61	1. The screen: MD300C61 is LED digital tube, MD300C is double-colour OLED. 2. PCB layout 3. The shape and size of shell
MD300C63	The shape and size of shell

3. Sponsor Information

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6. Proposed Device Information

Device Common or Usual Name: Pulse Oximeter
Device Trade or Proprietary Name: Fingertip Pulse Oximeter
Model: MD300C3/ MD300CF3/ MD300C310/ MD300C9111/ MD300C9211/ MD300C61/ MD300C63
Classification Name: Oximeter
Regulation Number: 21 CFR 870.2700
Product Code: DQA
Panel: Anesthesiology

7. Predicate Device

Fingertip Pulse Oximeter MD300C (K070371)
Beijing Choice Electronic Technology Co., Ltd.
Suite 418, Building D4, 83 Fuxin Road
Beijing, CHINA 100856

8. Device Description

The applicant devices of Fingertip Pulse Oximeters MD300C series are fingertip devices, which can display % SpO2 and pulse rate value.

The applicant devices consist of detector and emitter LED, signal amplify unit, CPU, data display unit and power unit.

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 photodetector in fingersensor 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 power source of the applicant devices is 2 AAA alkaline batteries. The applicant devices of MD300C3/ MD300CF3/ MD300C310 have pulse beep and sound tips function. The applicant devices of MD300C9111/ MD300C9211 have a USB port which can connect external probe.

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 10** Software.

9. Intended use

The Fingertip Pulse Oximeters, MD300C series, are portable, non-invasive devices intended for spot checking of arterial hemoglobin oxygen saturation (SpO2) and pulse rate of adult and pediatric patient at home and hospital (including clinical use in internist/surgery, Anesthesia, and intensive care units). Not for continuous monitoring.

10. Substantial Equivalence

The applicant devices of Finger Pulse Oximeters MD300C series have same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance effectiveness, performance safety as the predicate device Pulse Oximeter MD300C (K070371).

Specific model of MD300C series has specific difference with MD300C. These differences include adding pulse beep and sound tips function, adding a USB port to connect external probe, display screen and the shape & size of the shell. For adding pulse beep and sound tips function, MD300C series is safer than MD300C. For adding a USB port to connect external probe, we have conducted clinical trials according to ISO 9919. And the difference of display screen and shell is slight and dose not effluence the effectiveness and safety of the device.

The proposed devices are **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the subject devices are determined as safe and effectiveness.

11. Testing

The Fingertip Pulse Oximeters MD300C series are designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60601-1:1988+A1:1991+A2:1995, Medical Electrical Equipment – Part1: General requirements for safety.
- IEC 60601-1-2:2001+A1:2004, 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 the basic safety and essential performance of pulse oximeter equipment for medical use

The Fingertip Pulse Oximeters MD300C3/ MD300CF3/ MD300C310/ MD300C61/ MD300C63 share the same Blood Oxygen Module with the predicate device MD300C, so we believe the clinical test of these models can be exempted. The Fingertip Pulse Oximeters MD300C9111 and MD300C9211 were added a USB port to connect external probe compared with MD300C, and these two models share same Blood Oxygen Module and external probe, so we conducted clinical test for MD300C9111 with external probe M-50G and M-50H, the clinical test of MD300C9211 can be exempted.

The Clinical Test of MD300C9111 following ISO 9919:2005, Annex EE.4 was conducted in the lab of Beijing Friendship 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.

The clinical protocol for adult:

The study protocol is subjected to ISO 9919:2005 Annex EE. Procedures of testing required in EE.2 are adopted. SpO_2 readings of the pulse oximeter equipment MD300C9111 are compared with CO-oximeter SaO_2 values.

The protocol: 15 healthy adult are selected as subjects. The subjects should lie on beds. The pulse oximeter sensor M-50G is set to the subjects' index fingertip, and the sensor M-50H is set to the female subjects' little fingertips. Pulse oximeter sensors should better be covered with opaque material to prevent optical interference. The measuring value which is stabilized for more than 30

seconds can be considered as an endpoint. The readings of SpO_2 and pulse rate should be recorded.

Indication, scope, contraindication and caution:

The MD300C9111 pulse oximeter is appropriate to any person in the hospital and home.
It can not be used in the environment with flammable anesthetic gas.
It can not be used during the MRI and CT scanning.
The MD300C9111 pulse oximeter is intended for use only as an adjunct in patient assessment.
It must be used in conjunction with clinical signs and symptoms.

Conclusion:

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.

The accuracy of the proposed device is compliance to the requirement, and the product is safe during the use. It can be used in the clinical environment. It is substantially equivalent to other pulse oximeter product with the same effectiveness and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC - 8 2010

Beijing Choice Electronic Technology Company, Limited
C/O Ms. Diana Hong
Shanghai Midlink Business Consulting Company, Limited
Suite 5D, No. 19, Lane 999
Zhongshan No. 2
Shanghai China 20030

Re: K101577
Trade/Device Name: Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 2, 2010
Received: November 2, 2010

Dear Ms. Hong:

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,

for

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

Enclosure

Attachment VII

Indication for Use Form

510(k) Number: K101577

Device Name: Fingertip Pulse Oximeter

DEC 2 2010

Indications for Use:

The Fingertip Pulse Oximeters, MD300C series, are portable, non-invasive devices intended for spot checking of arterial hemoglobin oxygen saturation (SpO2) and pulse rate of adult and pediatric patient at home and hospital (including clinical use in internist/surgery, Anesthesia, and intensive care units). Not for continuous monitoring.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schuttens

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101577