K092652

510(k) Summary

JAN - 8 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92

The Assigned 510(k) Number is:

1. Statement: This is a special 510(k) report for Fingertip Pulse Oximeter MD300CA, which is a modification device to Pulse Oximeter MD300C (K 070371). The modification does not change intended use. And the new device has different trade name to predicate device.

The applicant device, Fingertip Pulse Oximeter MD300CA is a modification device to Pulse Oximeter MD300C (K 070371). The main modifications are listed below:

Item	MD300CA	MD300C
Enclosure Material	Medical Silicon	ABS
Battery	One button battery	Two AAA batteries

2. Applicant Device Information
Device Trade/Proprietary Name: Fingertip Pulse Oximeter MD300CA
Device Classification Name: Oximeter
Product Code: DQA
Regulation Number: 870.2700
Device Class: II
Review Panel: Anesthesiology
Intended Use:

The MD300CA Fingertip Pulse Oximeter is a portable oximeter intended for spot-check use to non-invasively measure oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients at home and hospital settings (including clinical use by internists, during surgery, anesthesia, intensive care, etc.). Not for continuous monitoring.

3. Submitter Information
Manufacturer Name:

Beijing Choice Electronic Technology Co., Ltd.
Room 1127-1128 Building B, Bailangyuan
Fuxing Road , No. A36 Beijing, CHINA 100039

Contact Person of the Submission:

Mr. Lei Chen
No.9 Shuangyuan Road

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4. Predicate Device

Fingertip Pulse Oximeter MD300C
K-number: K 070371
Product Code: DQA
Intended Use:
The MD300C Fingertip Pulse Oximeter is a portable non-invasive, spot-check, 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 and etc). Not for continuously monitoring.

Manufactured by:
Beijing Choice Electronic Technology Co., Ltd.
Room 1127-1128 Building B, Bailangyuan
Fuxing Road , No. A36
Beijing, CHINA 100039

5. Device Description

The applicant device of Fingertip Pulse Oximeter MD300CA can display %SpO_2, pulse rate value and vertical bar graph pulse amplitude.

The applicant device consists of a detector and emitter LED, signal amplify unit, CPU, data display unit, and power unit.

The Finger 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 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 device has low battery voltage alarm function and automatically power of function. The power source of the applicant device is 1 button lithium battery.

The applicant device is not for life-supporting or life-sustaining, not for implant. The

device or transducers are not sterile and the transducer does not need sterilization and the transducer is reusable but does not need re-sterilization since it is not sterile. The device is not for prescription. The device does not contain drug or biological products.

The device is electrically operated and the Electrical Safety Test report of TRS09040017 and Electromagnetic Compatibility Test report of TRE09050008 following IEC 60601-1-2 with was conducted as the environmental test for the home use. Please see the **Appendix II** Electrical Safety and EMC Test.

The device is software-driven and the software validation is provided in **Chapter VIII** Software Validation.

The Performance Test reports regarding with safety and effectiveness test of the safety mechanism preventing the excess current from leading to burning injury to user **(Report No. MD300CA-01-001)** and Low-Voltage Alarm System **(Report No. MD300CA-01-002)** are presented in **Appendix III** Performance Bench Test.

The Clinical Test reports following ISO 9919:2005, Medical electrical equipment Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use are conducted in Laboratory of Beijing Friendship Hospital provided in **Appendix IV** Clinical Test Reports.

All applicable standards are listed in **Chapter II** Standards.

The device is not kit.

6. Effectiveness and Safety Considerations

Effectiveness:
The Clinical Test reports following ISO 9919:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance accuracy of pulse oximeter equipment for medical use are conducted in Beijing Friendship Hospital provided in **Attachment IV** Clinical Test Reports.
The accuracy of MD300CA fingertip pulse oximeter equipment 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.

Safety Consideration:
The Performance Test reports regarding with safety and effectiveness test of the safety mechanism preventing the excess current from leading to burning injury to user **(Report No. MD300CA-01-001)** and Low-Voltage Alarm System **(Report No. MD300CA-01-002)** are presented in **Attachment III** Performance Bench Test.
The test results of biocompatibility of all the skin-contacting material are presented as

Table IV-2 for the consideration of Biological Specifications. Please see **Appendix I** Biocompatibility Reports.
The Biological Evaluation Tests are in compliance with the standards of ISO 10993 "Biological Evaluation of Medical Devices". The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility
The applicant device is compliance with IEC60601-1, Medical electrical equipment Part 1: General requirements for safety and IEC60601-1-2, Medical electrical equipment – Part 1-2: General requirements for safety -Collateral standard: Electromagnetic compatibility -. Requirements and tests

6. Substantially Equivalence Determination

Comparison Analysis

The applicant device has same classification information, same indications and intended use, same design principle, same software, similar product design and specifications, same performance effectiveness, performance safety as the predicate device. The only difference is Main Material, the battery type, working time. These differences are slight and do not effluence the effectiveness and safety of the device.

Conclusion:
The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 8 2010

Mr. Lei Chen
Beijing Choice Electronic Technology Company, Limited
No. 9 Shuangyuan Road
Badachu Hi-tech Zone, Shijingshan District
Beijing
CHINA 100041

Re: K092652
Trade/Device Name: Fingertip Pulse Oximeter MD300CA
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 11, 2009
Received: December 11, 2009

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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

Indication For Use

510(k) Number (if known): Pending

Device Name: Fingertip Pulse Oximeter MD300CA

Indications for Use:

The MD300CA Fingertip Pulse Oximeter is a portable Oximeter intended for spot-check use to non-invasively measure oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patient at home and hospital settings (including clinical use in internist/ surgery, Anesthesia, intensive care and etc). Not for continuously monitoring.

Prescription Use ✓ 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 Schultheiss

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

510(k) Number: K092652