JUL - 2 2008

K081125

510(k) Summary

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 Wrist Pulse Oximeter MD300W, which is a modification device to Pulse Oximeter MD300I (K072825). The modification does not change intended use. And the new device has different trade name to predicate device.

The applicant device, Wrist Pulse Oximeter MD300W is a modification device to Pulse Oximeter MD300I (K 072825). The main modifications are listed below:

Item	MD300W	MD300I
Display type	1 types	3 types
Display mode	Segment LCD (black & white)	OLED (double color)
Display	%SpO2, Pulse Rate Value and vertical bar graph pulse amplitude	%SpO2, Pulse Rate Value and vertical bar graph pulse amplitude, Pulse Waveform

2. Applicant Device Information

Device Trade/Proprietary Name: Wrist Pulse Oximeter MD300W
Device Classification Name: Oximeter
Product Code: DQA
Regulation Number: 870.2700
Device Class: II
Review Panel: Anesthesiology
Intended Use:

The MD300W wrist oximeter 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. 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 Wang
East Building 3F, No.5 Shixing Street
Badachu Hi-tech Zone,Shijingshan District
Beijing China 100041
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Email: wanglei@choicemmed.com

4. Predicate Device

Pulse Oximeter MD300I
K-number: K072825
Product Code: DQA
Intended Use:

Pulse Oximeter MD300I 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.

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 Wrist Pulse Oximeter MD300W is a wrist-worn device, which can display %SpO2, pulse rate value and vertical bar graph pulse amplitude.

The applicant device consists of sensor, signal amplify unit, CPU, data display unit, data transmit unit, storage and power unit.

The wrist 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 SpO2.

The applicant device has low battery voltage alarm function and automatically power of function. The power source of the applicant device is 1 AAA alkaline batteries.

The applicant device is not for life-supporting or life-sustaining, not for implant. The device or sensor are not sterile and the sensor does not need sterilization and the sensor is reusable but does not need re-sterilization since it is not sterile. The device is for prescription. The device does not contain drug or biological products.

The device is electrically operated and the Electrical Safety Test report of BJ07013-1 and Electromagnetic Compatibility Test report of BJ7901018-1 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. MD300W-01-001)** and Low-Voltage Alarm System **(Report No. MD300W-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 Wulanchabu City Center Hospital provided in **Attachment IV** Clinical Test Reports.

The accuracy of MD300W 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. MD300C-01-001)** and Low-Voltage Alarm System **(Report No.**

MD300C-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, similar product design and specifications, sam performance effectiveness, performance safety as the predicate device. The only difference is Working time, Relative humidity. 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
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2008

Mr. Lei Wang
Product Manager
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Room 1127-1128 Building B
Bailangyuan Fuxing Road #A36
Beijing
CHINA 100041

Re: K081125
Trade/Device Name: Wrist Pulse Oximeter MD300W
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 28, 2008
Received: June 2, 2008

Dear Mr. Wang:

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.

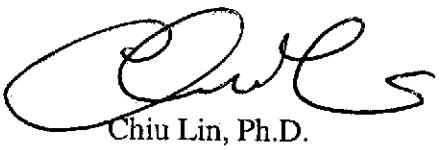
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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: Wrist Pulse Oximeter MD300W

Indications for Use:

The MD300W wrist oximeter 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.

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)

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

510(k) Number: K091125