Exhibit I 510(K) Summary

As required by 21 CFR 807.92
The Assigned 510(K) Number is: K111494

1. Date Prepared: December 16, 2011

2. Sponsor Information

Beijing Choice Electronic Technology Co., Ltd.
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3. Submission Correspondent

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4. US Agent

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5. Proposed Device Information

Device Common or Usual Name: Pulse Oximeter
Device Trade or Proprietary Name: Handheld Pulse Oximeter
Model: MD300M122, MD300M222, MD300M322
Classification Name: Oximeter
Regulation Number: 21 CFR 870.2700
Product Code: DQA
Panel: Anesthesiology

6. Predicate Device

Fingertip Pulse Oximeter MD300C318 (K092620)
Beijing Choice Electronic Technology Co., Ltd.
Room 1127-1128 Building B, Bailangyuan
Fuxing Road, No.A36
Beijing, CHINA 10039

7. Device Description

- **MD300M122 Handheld Pulse Oximeter**

The applicant device MD300M122 Handheld Pulse Oximeter is integrated with Bluetooth® technology allowing the user to transfer measurement data any time and anywhere. The oximeter is designed with the measurement, storage, review, visible and audible alarms and data transmission function.

The MD300M122 Handheld Pulse Oximeter works by applying a external sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 940nm, which is infrared light.

The applicant device of MD300M122 Handheld Pulse Oximeter is the handheld equipment, which mainly function are measurement, display, alarm, data storage & replay etc.

Measurement function
That's the mainly function of the device, which use the method described above to measure the SpO2 value and Pulse Rate value of user.

Display function
The display function of the device display the SpO2&PR value, waveform synchronously, battery capacity indicator, alarm state indication and time.

Alarm function

The applicant device has physiological alarm function as SpO2 and PR parameter and technology alarm function as Low Battery Voltage, probe off and Finger out.

Each alarm of device contains VISUAL and AUDIBLE alarm. And you can turn on or off the alarm and set the alarm limits.

There are three-level alarm priorities in Oximeter. All the three priorities divided by built-in module and can't be changed by user.①High priority: "Di- Di - Di ----- Di – Di" indicates the patient is in the very dangerous situation.②Medium priority: "Di - Di - Di" indicates the warning-attention should be paid.③Low priority: "Di" indicates the technical alarm caused by the device itself.

Data storage, replay & transmission function

The measured record is stored automatically every four seconds. The monitor can store 72 hours records.

The device includes the function as "record review" on the Oximeter equipment. And you can review "Data Browse", "SpO2 Trend", "PR Trend" and "Data Clear" by this function. The data stored in the device can be transmitted through Bluetooth or USB cable.

Power

The applicant device uses three AA alkaline batteries or rechargeable batteries for power supply. The device has charge function by AC/DC power adapter, the specification of which is: 100-240 (VAC), 47/63 (Hz) input; 5Vd.c. output.

The device can measure normally during the process of charging, but we won't recommend to do so.

The applicant device is not for life-supporting or life-sustaining, not for implant. The device is not sterile and does not need sterilization or re-sterilization. The device is for prescription. The device does not contain drug or biological product.

The device is software-driven and the software validation is provided in **Section 10 Software.**

- **MD300M222 Handheld Pulse Oximeter**

MD300M222 is the same as MD300M122 except the appearance.

- **MD300M222 Handheld Pulse Oximeter**

MD300M322 is the same as MD300M122 except the appearance.

8. Intended use

The MD300M122/MD300M222/MD300M322 handheld pulse oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult and pediatric patients in hospitals and home care.

9. Substantial Equivalence

The applicant devices MD300M122/MD300M222/MD300M322 Handheld Pulse Oximeter have the same classification, same intended use, same design principle, similar specifications and same safety performance as the predicate device. These are no obvious differences to influence the effectiveness and safety of the device.

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

10. 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 proposed device was performed the tests according to 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.

FCC PART 15, SUBPART C: 2008 (Senction 15.249)

The Clinical Tests following ISO 9919:2005, Annex EE.2 are conducted in the lab of Beijing Military General Hospital. The study protocol is subjected to ISO 9919:2005 Annex EE. Procedures of testing required in EE.2 are 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.

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

Ms. Sunny Wang
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JAN 18 2012

Re: K111494
Trade/Device Name: Handheld Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 16, 2011
Received: December 19, 2011

Dear Ms. 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. 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,

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

Indications for Use

510(k) Number (if known): pending

Device Name: Handheld Pulse Oximeter

Indications for Use:

The MD300M122/MD300M222/MD300M322 handheld pulse oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (SpO2) and pulse rate (PR) of single adult and pediatric patients in hospitals and home care.

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 IF NEEDED)

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for Lester Schultheis

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

510(k) Number: K111494