DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 13, 2015

Beijing Choice Electronic Technology Co., Ltd.
c/o Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 237-023
Shanghai, 200237
CHINA

Re: K141024
Trade/Device Name: External Pulse Oximeter, Models MD50I and MD50P
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 5, 2014
Received: December 8, 2014

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

Exhibit #5 Indications for Use

510(k) Number: K141024
Device Name: External Pulse Oximeter (MD50I, MD50P)

Indications for Use:

The external pulse oximeter (MD50i and MD50p) is designed for spot checking of the pulse oxygen saturation and pulse rate for adult at hospital. This medical device can be reused. Not for continuous monitoring.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Exhibit #6 510(k) Summary

This 510(k) Summary of 510(k) substantial equivalence information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _K141024_____

1. Date of Submission: Apr. 18, 2014

2. Sponsor

   Beijing Choice Electronic Technology Co., Ltd
   Rm 1127-1128, Fuxing Road, A36, 100039 Beijing,China

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3. Submission Correspondent
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   Fax: 240-238-7587
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4. Proposed Device Identification

   Proposed Device Name: External Pulse Oximeter
   Proposed Device Model: MD50I / MD50P
   Device Common Name: Pulse Oximeter

   Classification: 2
   Product Code: DQA
   Regulation Number: 21 CFR 870.2700
   Review Panel: Anesthesiology

Intended Use Statement:

The external pulse oximeter (MD50i and MD50p) is designed for spot checking of the pulse oxygen saturation and pulse rate for adult at hospital. This medical device can be reused. Not for continuous monitoring.

5. Predicate Device Identification

510(k) Number:k093757
Product Name: MD300C1 Fingertip pulse oximeter
Manufacturer: Beijing Choice Electronic Technology Co., Ltd

6. Device Description

The MD50I includes three main parts as SpO2 probe, SpO2 module and 30 pin port. The SpO2 probe is used to collect the SpO2 and PR signal from the patient, the SpO2 module is used to process the signal from the probe and transform it to digital signal, the 30 pin port is used to connect with iPhone device for digital signal transmission.

The MD50I includes two parts of software, Upper Computer software (Mobile App) and Low Computer Software.

The Upper Computer software is installed in the iPhone device, which is used to receive the measured data (SpO2 and PR) from the MD50I, which has the following functions:

- Measured data (SpO2 and PR) receiving;
- Display the measured data (SpO2 and PR) in real time;
- Graph of the measured data (SpO2 and PR) based on the day/week/month or all of observed data trend.
- Measured data (SpO2 and PR) reviewed, the day/week/month history data could be reviewed;
- Note function, the user can make comments after specified history record;
- History data delete, the user can delete the history records;
- Personal information edit, the user can input their own information and save it;
- Share function, the user can select the specified history record to share with others by email;

The Low computer software is embedded in the MD50I, which includes the SpO2 sensor and has the following functions:

- Collect the SpO2 and PR data from patient;
- Transform the electrical signal to digit signal;
- Send the digit signal to the Upper Computer software for display and following process.

The MD50P includes three main parts as SpO2 probe, SpO2 module and USB plug. The SpO2 probe is used to collect the SpO2 and PR signal from the patient, the SpO2 module is used to process the signal from the probe and transform it to digital signal, the USB is used to connect with PC device for digital signal transmission.

The MD50P includes two parts of software, Upper Computer software (PC App) and Low Computer Software.

The Upper Computer software is install in the PC device, which is used to receive the measured data (SpO2 and PR) from the MD50P, which has the following functions:

- Insert device identified automatically;
- Measured data (SpO2 and PR) receiving;
- Display the measured data (SpO2 and PR) in real time;
- Oxygen saturation, Pulse rate, Pulse bar and waveform are clearly displayed on PC when doing real-time measuring;
- Save the current data into your PC with the format of "txt", "pdf", "xls";
- Data print;
- Personal information edit, the user can input their own information and save it, such as title, patient ID, name, gender, age, height, weight, physician comments;
- Alarm set, set the high/low SpO2 limit and high/low PR limit;
- Saved data reviewed.
- Login interface, the user needs input password and user name to access the account.

The Low computer software is embedded in the MD50P, which includes the SpO2 sensor and has the following functions:

- Collect the SpO2 and PR data from patient;
- Transform the electrical signal to digit signal;
- Send the digit signal to the Upper Computer software for display and following process.

7. Non-Clinical Test Conclusion

The proposed devices are handheld, internal power, BF device, the test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007), Medical electrical equipment– Part 1: General requirements for basic safety, and essential performance.
IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements andtests.
ISO 80601-2-61:2011,Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

The SpO2 probe used with proposed device, which includes patient contacting material (silicone), is manufactured by Beijing Choice Electronic Technology CO. Ltd., and has been cleared by FDA in Mar. 04, 2009 as K082487, and compliance the following biocompatibility standard.
ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

In addition to the above tests, the following tests were performed to evaluate the performance of the device:

Test Type	***Test Method***	***Acceptance Criteria***	***Conclusion***
Main Function	Operate the device as the instruction, and check whether or not the main function meet the design specification	The main function of device shall be meet the design specification	PASS
SpO_2Accuracy	Connect the device with SpO_2 simulator, use the simulator output the SpO_2 value, and check the SpO_2 measurement range, display range and resolution.	Measurement Range: 70%-90% Display Range: 0%-99% Resolution: ±1%	PASS
Pulse Rate (PR) Accuracy	Connect the device with SpO_2 simulator, use the simulator output the PR value, and check the PR measurement range, display range and resolution.	Measurement Range: 30-235 bpm Display Range: 0-255 bpm Resolution: ±1bpm	PASS
SpO2/PR response time	Connect the device with SpO2 simulator, use the simulator output the SpO2 and PR value, and measure the max. and average response time of SpO2/PR	The max. response time shall be less than 45 s; The average response time shall be less than 30 s;	PASS
Environmental Test	SpO_2Accuracyand Pulse Rate (PR) Accuracy tests were performed in the following conditions respectively: a. Normal Condition; b. High temperature storage condition; c. Hot and humid storage condition	MD50I SpO2: 70%~99%, ±2% PR: ±2 bpm (30-99bpm) or ±2% (100-235bpm) MD50P SpO2: 70%~99%, ±3% PR: ±2 bpm (30-99bpm) or ±2% (100-235bpm)	PASS
SpO2/PR accuracy under low perfusion condition	SpO_2Accuracyand Pulse Rate (PR) Accuracy tests was performed under low perfusion condition.	MD50I SpO2: 70%~99%, ±2% PR: ±2 bpm (30-99bpm) or ±2% (100-235bpm) MD50P SpO2: 70%~99%, ±3% PR: ±2 bpm (30-99bpm) or ±2% (100-235bpm)	PASS
Shelf Life Test	Bench Test was performed on accelerated aged samples.	The test samples after test should meet the following condition: No deformation on the	

		sample; No abnormal or structure loosen on the sample; The performance meet the design specification;	
Performance Test after Cleaning and Disinfection	SpO_2Accuracyand Pulse Rate (PR) Accuracy tests was performed on samples subject to 5000 cycles cleaning and disinfection.	MD50I SpO2: 70%~99%, ±2% PR: ±2 bpm (30-99bpm) or ±2% (100-235bpm) MD50P SpO2: 70%~99%, ±3% PR: ±2 bpm (30-99bpm) or ±2% (100-235bpm)	PASS

8. Clinical Trial Conclusion

MD50I External Pulse Oximeter

As part of final product validation for Beijing Choice Electronic Tech Co. Ltd MD50I External Pulse Oximeter on iPod Touch4, and SpO2 accuracy investigation was completed. The study was conducted in accordance to EN ISO 14155-1:2009, EN ISO 14155-2:2009, ISO 9919:2005, EN ISO 9919:2009, BS EN ISO 80601-2-61:2011, and the FDA guidance Document for pulse oximeters.

The purpose of this study was to evaluate the SpO2 accuracy performance of the MD50I External pulse oximeter on iPod Touch4, during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to arterial blood CO-Oximetry.

After Institutional review board approval, 12 healthy adult volunteer subjects (ages 21-33yr, 46-75kg, 158-183cm, with light to dark pigmentation) were included in the study conducted July. 5-6, 2013 to evaluate the SpO2 accuracy performance of the MD50I External Pulse Oximeter on iPod Touch 4, and11 subjects completed the test as effective data collection for final data analysis, the 1 subject was excluded during testing process, because the unstable pulse rate.

Each system was evaluated during steady state/non-motion conditions with various levels of induced hypoxia resulting in stable oxygen saturation levels between 100% and 70% SaO2. Arterial blood samples were drawn during simultaneous data collection from the test devices. The blood was immediately analyzed on reference CO-Oximetry providing functional SaO2 for the basis of the SpO2 accuracy comparison.

The SpO2 accuracy performance results showed the MD50I External Pulse Oximeter on iPod Touch4 to have and Arms of 1.48 during steady state conditions over the range of 70-100%

MD50P External Pulse Oximeter

As part of final product validation for Beijing Choice Electronic Tech Co. Ltd MD50P External Pulse Oximeter on DELL vostro 1400 PC, an SpO2 accuracy investigation was completed. The study was conducted in accordance to EN ISO 14155-1:2009, EN ISO 14155-2:2009, ISO 9919:2005, EN ISO

9919:2009, BS EN ISO 80601-2-61:2011, and the FDA guidance Document for pulse oximeters.
The purpose of this study was to evaluate the SpO2 accuracy performance of the MD50P External pulse oximeter on DELL vostro 1400 PC, during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to arterial blood CO-Oximetry.
After Institutional review board approval, 12 healthy adult volunteer subjects (ages 21-33yr, 46-75kg, 158-183cm, with light to dark pigmentation) were included in the study conducted July. 5-6, 2013 to evaluate the SpO2 accuracy performance of the MD50P External Pulse Oximeter on DELL vostro 1400 PC, and 11 subjects completed the test as effective data collection for final data analysis, the 1 subject was excluded during testing process, because the unstable pulse rate.
Each system was evaluated during steady state/non-motion conditions with various levels of induced hypoxia resulting in stable oxygen saturation levels between 100% and 70% SaO2. Arterial blood samples were drawn during simultaneous data collection from the test devices. The blood was immediately analyzed on reference CO-Oximetry providing functional SaO2 for the basis of the SpO2 accuracy comparison.
The SpO2 accuracy performance results showed the MD50P External Pulse Oximeter on iPod Touch4 to have and Arms of 2.08 during steady state conditions over the range of 70-100%

9. Substantially Equivalent

Table III-1 General Comparison

ITEM	Proposed Device External Pulse Oximeter (MD50I & MD50P)	Predicate Device MD300C1 Fingertip pulse oximeter (k093757)	Remark
Product Code	DQA	DQA	SE
Regulation No.	21 CFR 870.2700	21 CFR 870.2700	SE
Class	2	2	SE
Intended Use	The external pulse oximeter (MD50i and MD50p) is designed for spot checking of the pulse oxygen saturation and pulse rate for adult at hospital. This medical device can be reused. Not for continuously monitoring.	MD300C1 Finger pulse 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.	SE
Measurement Principle	Beer-Lambert law according to Spectrum Absorption characteristics of Hb and HbO2 in irradiation zones of red and near-infrared light.	Beer-Lambert law according to Spectrum Absorption characteristics of Hb and HbO2 in glow and near-infrared zones.	SE
Technical Features	Finger clip type oximeter, the sensor is separated from other function, the independent cable is used to connect the sensor with other parts for data collection	Finger clip type oximeter, integrate the sensor, measured data display and measurement control operation in one device.	Analysis 1

	and control.		

The proposed device has the different technical features, such as above, with predicate device for operation, but this difference only could affect data's accuracy of transfer and display, we have conducted the perform tests for data accuracy, include clinical trial, all test result of data displayed meet the requirements.

Therefore, the difference does not adversely impact substantial equivalence.

Table III-2Performance Comparison

ITEM	Proposed Device External Pulse Oximeter (MD50I & MD50P)	Predicate Device MD300C1 Fingertip pulse oximeter (k093757)	Remark
Measurement wavelength	Red: 660nm Infrared: 940nm	Red: 660nm Infrared: 940nm	SE
SpO_2measurement range	70%-99%	70%-99%	SE
SpO_2accuracy	70%~99%, ±2% (MD50I); ±3%(MD50P)	70%~99%, ±3%	SE
SpO_2resolution	±1%	1%	SE
PR measurement range	30-235 bpm	30~254bpm	Analysis 2
PR accuracy	±2 bpm (30-99 bpm) or ±2% (100-235 bpm)	±2 bpm or ±2%	SE
PR resolution	±1 bpm	1bpm	SE
Data update time	<15s	<15s	SE

Analysis 2:

The PR measurement range of the proposed device is different than that of the predicate device. But the measurement range is considered to be able to cover the general pulse rate of healthy people and patients. In addition, the PR measurement range is clearly on the proposed labeling to remind the user. Therefore, the difference does not adversely impact substantial equivalence.

Table III-3Safety Comparison

ITEM	Proposed Device External Pulse Oximeter (MD50I & MD50P)	Predicate Device MD300C1 Fingertip pulse oximeter (k093757)	Remark
Power Supplier	5V form PC or 3.3 V form iOS mobile device	2 A AA alkaline batteries	Analysis 3
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Patient Contact Material	Silicone	Silicone	SE
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE
Level of Concern of the Software	Moderate	Moderate	SE

Analysis 3:

The power supplier of the proposed device is different than that of the predicate device. But all power supplier are in compliance with the requirements of IEC60601-1. Therefore, the difference does not adversely impact substantial equivalence.

The proposed device, External Pulse Oximeter (MD50I, MD50P), is determined to be Substantially Equivalent (SE) to the predicate device, MD300C1 Fingertip pulse oximeter (k093757).

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