DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 13, 2015

Shanghai Berry Electronic Tech Co., Ltd
% Mr. Ray Wang
Official Correspondent
Beijing Believe Tech. Service Co., Ltd.
1-202, Build 3, Beijing New World, No.5 Chaoyang Road
Chaoyang District, Beijing, 100024
CHINA

Re: K142687
Trade/Device Name: Pulse Oximeter (BM1000A/ BM2000A)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 5, 2015
Received: March 12, 2015

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. 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" (21 CFR 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 Radiological Health

Enclosure

Exhibit #2 Indications for Use

510(k) Number: K142687
Device Name: Pulse Oximeter (BM1000A/ BM2000A)

Indications for Use:

The pulse oximeter (BM1000A & BM2000A) is designed for spot checking of the pulse oxygen saturation and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously monitoring.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(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)

Exhibit #3 510(k) Summary

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

The assigned 510(k) Number: _____

1. Date of Preparation: Sept. 11, 2014

2. Sponsor

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3. Submission Correspondent
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4. Proposed Device Identification

   Proposed Device Name: Pulse Oximeter
   Proposed Device Model: BM1000A/ BM2000A
   Device Common Name: Pulse Oximeter

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

Intended Use Statement:

The pulse oximeter (BM1000A & BM2000A) is designed for spot checking of the pulse oxygen saturation and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously 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 proposed device, pulse oximeter, includes two models in this application, BM1000A and BM2000A. The two proposed devices all are handheld device with detachable SpO2 sensor, the BM1000A work with the SpO2 sensor BSA09001P and the BM2000A work with the SpO2 sensor BST09001S; they share the following same features:

★ Spot check and display SpO2 and PR value;
★ Low battery capacity indicator;
★ Finger off indicator;

The pulse oximeter (BM1000A & BM2000A) is designed for spot checking of the pulse oxygen saturation and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously monitoring.

The proposed device is not provided sterile and is not a reprocessed single-use device.

7. Non-Clinical 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 test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2012, 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 and tests.
ISO 80601-2-61:2011,Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
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.

8. Clinical Trial Conclusion

The clinical trial was performed according to Clause 201.12.1.101.2 and Annex EE.2 of ISO 80601-2-61:2011 *Procedure for invasive laboratory testing on healthy volunteers.*

A radial arterial cannula was placed in either the left or right wrist of each subject. Blood gas analysis to determine oxyhemoglobin saturation was performed on an OSM-3® multi-wavelength oximeter (Hemoximeter, Radiometer, Copenhagen). No subject was anemic (Hemoglobin _ 10gm•dl-1). Each subject had control data taken at the beginning of each experiment, with two control blood samples drawn while breathing room air. Hypoxia was induced to different levels of oxyhemoglobin saturation (between 70-100%) by having subjects breathe mixtures of nitrogen, room air, and carbon dioxide. Oxyhemoglobin saturation was reduced to a series of targets and stabilized at the plateau value. Each plateau level of oxyhemoglobin saturation was maintained for at least 30 seconds. Two arterial blood samples were then obtained, approximately 30 seconds apart. A total of 24 samples were obtained per subject. Data were recorded by Bickler-Ye lab and provided for analysis.

It can be determined from the result of the clinical study that the accuracy Arms of the proposed device is smaller than 3%.

9. Substantially Equivalent

Table III-1 Substantially Equivalent Comparison

ITEM	Proposed Device Pulse Oximeter (BM1000A & BM2000A)	Predicate Device MD300C1 Fingertip pulse oximeter (k093757)
Product Code	DQA	Same
Regulation No.	21 CFR 870.2700	Same
Class	2	Same
Intended Use	The pulse oximeter (BM1000A & BM2000A) is designed for spot checking of the pulse oxygen saturation and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously monitoring.	Same
SpO_2measurement range	0-100%	Same
SpO_2accuracy	70%-100%, ±3%; Undefined for <70%	Same
PR measurement range	25-250 bpm	Similar
PR accuracy	±2 bpm	Same
Power Supplier	BM1000A: 2AA Batteries	Similar

		BM2000A: Li ion battery	
Technical Characteristics	Device Form	Handheld Pulse Oximeter with separate sensor	Similar
	Sensor type	BM1000A: wrap type BM2000A: Fingertip type	Similar
	Display Information	SpO2 measurement data PR measurement data Battery and finger off indicator SpO2/PR alarm setting (BM1000A only)	Same
Electrical Safety		Comply with IEC 60601-1	Same
EMC		Comply with IEC 60601-1-2	Same

Difference in SpO2 accuracy, PR measurement range and Power supplier between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

There are several different in Technical Characteristics between the proposed and predicate device:

a. The proposed device has different device form with the predicate device, but all proposed devices have same measurement principle with predicate device, and all proposed devices meet the requirements of ISO 80601-2-61. Therefore, this difference is considered to have no effect on effectiveness and safety.
b. The proposed device has different sensor type with the predicate device, but all sensors have same measurement principle with predicate device, and all sensors meet the requirements of ISO 80601-2-61. Therefore, this difference is considered to have no effect on effectiveness and safety.

The proposed device, Pulse Oximeter (BM1000A & BM2000A), is determined to be Substantially Equivalent (SE) to the predicate device, MD300C1 Fingertip pulse oximeter (k093757).