April 4, 2018

Shanghai Berry Electronic Tech Co., Ltd
% Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-402, Building #27, No. 56, LiangXiang East Rd.,
FangShan District
Beijing, 102401 CN

Re: K172141
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 1, 2018
Received: March 5, 2018

Dear Ray 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172141

Device Name
Pulse Oximeter

Indications for Use *(Describe)*
The pulse oximeter (BM1000 & BM1000C) is designed for spot checking of the functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously monitoring.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Tab #3 510(k) Summary

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

The assigned 510(k) Number: K172141

1. Date of Preparation: 03/27/2018

2. Sponsor Identification

Shanghai Berry Electronic Tech Co., Ltd
Unit C, 1st Floor, 7th Building, No.1188 Lianhang Road, Minhang District,Shanghai, China 201112
Establishment Registration Number: 3009241523

Contact Person: Xuezhi Yin
Position: General Manager
Tel: +86-21-5853 1958
Fax: +86-21-5853 0468
Email: berrymedical@hotmail.com

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe Technology Service Co., Ltd.
5-402, Building #27, YangGuangYiShang, No. 56, LiangXiang East Rd.,
FangShan District, BeiJing, China 102401

Tel: +86-18910677558
Fax: +86-10-80337041
Email: **ray.wang@believe-med.com**

4. Identification of Proposed Device

Trade Name: Pulse Oximeter
Common Name: Pulse Oximeter
Model(s): BM1000/BM1000C

Regulatory Information
Classification Name: Oximeter
Classification:II
Product Code:DQA
Regulation Number: 21 CFR 870.2700
Review Panel:Anesthesiology;

Intended Use Statement:

The pulse oximeter (BM1000 & BM1000C) is designed for spot checking of the functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously monitoring.

Device Description

The proposed device, pulse oximeter, includes two models in this application, BM1000 and BM1000C. The two proposed devices all are fingertip device; they are share the following same features:

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

Beside the features above, the BM1000 can display Plethysmogram wave, but the BM1000C deoesn't have this function.

The pulse oximeter (BM1000 & BM1000C) is designed for spot checking of thefunctional oxygen saturation of arterial hemoglobin (SpO2) 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.

5. Identification of Predicate Device(s)

Predicate Device ：

510(k) Number: K141362
Product Name: Pulse Oximeter CMS50EW

Model Name: CMS50EW

Manufacturer:

Contec Medical System Co., Ltd.

6. Non-Clinical Test Conclusion

Non clinical 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:

a. IEC 60601-1:2005/A1:2012, Medical electrical equipment– Part 1: General requirements for basic safety, and essential performance.
b. IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
c. ISO 80601-2-61:2011,Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
d. ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
e. ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
f. Shelf Life Testing
g. SpO2 Accuracy and Pulse Rate Accuracy Performance Testing (Test after the repeated clean & disinfection conditions).
h. SpO2 Accuracy and Pulse Rate Accuracy Performance Testing (Test under the normal conditions).
i. SpO2 Accuracy and Pulse Rate Accuracy Performance Testing (Test under the low perfusion conditions).
j. SpO2 Accuracy and Pulse Rate Accuracy Performance Testing (Test under the wireless Bluetooth conditions without outside interference).
k. SpO2 Accuracy and Pulse Rate Accuracy Performance Testing (Test under the wireless Bluetooth conditions with outside interference).
l. Wireless coexistence testing.
m. FCC Part 15C Testing.
n. Software Validation and Verification Testing.

7. Clinical Test 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.*

The purpose of the clinical trial was to evaluate the SpO2 accuracy performance of the BM1000C Fingertip Pulse Oximeter 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 (IRB) approval, 12 healthy adult volunteer subjects (ages 20-41yr, 42-95kg, 155-181cm, with light to dark pigmentation) were included in the study conducted Nov. 9-10,

2013 to evaluate the SpO2 accuracy performance of proposed devices.

The 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.

No adverse effects or complications occurred during the study.

The SpO2 accuracy performance results showed the fingertip pulse oximeter to have an Arms of 1.50 (BM1000C) during steady state conditions over the range of 70-100%.

Because the BM1000C and BM1000 has only difference as Plethysmogram wave display, no difference would effects the measurement accuracy, so the clinical test result of BM1000C could be consider as applicable to BM1000.

8. Substantially Equivalent (SE) Comparison

Table 7-1 Comparison of Technology Characteristics

ITEM		Proposed Device Pulse Oximeter (BM1000 & BM1000C)	Predicate Device Pulse Oximeter CMS50EW (K141362)	Remark
Product Code		DQA	DQA	SE
Regulation No.		21 CFR 870.2700	21 CFR 870.2700	SE
Class		2	2	SE
Intended Use		The pulse oximeter (BM1000 & BM1000C) is designed for spot checking of the functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously monitoring.	The Pulse Oximeter CMS50EW is a non-invasive device intended for spot-check or continuous monitoring of non-invasive oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate through the finger of adult patients in home and hospital environments (including clinical use internist/surgery,anesthesia, and intensive care settings). The device is reusable and not intended for out-of-hospital transport use.	Analysis 1
Features	BM1000	%SpO2 and PR measurement, Plethysmogram wave, Bluetooth	%SpO2 and PR measurement, Pulse bar, Pulse wave Alarm function, Bluetooth	SE
	BM1000C	%SpO2 and PR measurement, Bluetooth		SE
configuration		Fingertip	Fingertip	SE
SpO_2 measurement range		0%-100%	0%-100%	SE
SpO_2accuracy		±3% (70%~100%); Undefined for <70%	70%~100%:±2% , 0~69%,unspecified	Analyse 2
PR measurement range		25~250bpm	30bpm~250bpm	Analyse 3
PR accuracy		±2 bpm	±2bpm or ±2% (select the larger)	SE
Power Supplier		Two 1.5V AAA alkaline batteries	Voltage 3.7 rechargeable lithium battery	Analyse 4
Wireless Connection		Bluetooth	Bluetooth	SE

The data transported via wireless connection	SpO2 value, PR value and Pulse Bar	SpO2 value, PR value, Pulse Wave, Pulse Bar and Alarm Set parameters	Analyse 5
Data received terminal	Smart Phone loaded App	PC with BT adaptor	
Terminal Functions	SpO2 display, PR display, Pulse Bar display, data storage, history data trend drawn, User Registration	SpO2 display, PR display, Pulse Wave display, Pulse Bar display, alarm limits setting, data storage, history data trend drawn, User information management, print report	
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
Performance	Comply with ISO 80601-2-61	Comply with ISO 80601-2-61	SE
Biocompatibility	ISO10993-5&ISO10993-10	ISO10993-5&ISO10993-10	SE
Label and Labeling	Meet FDA’s Requirements	Meet FDA’s Requirements	SE

SE Analysis :

The proposed device has same classification, similar indication for use, similar technical specifications, same applied Standards with the predicate device.

The main differences are included as followings:

Analysis 1: The indication for use of proposed device is different than predicate device, but the differences are indication reduction, the proposed device does not include the indications, such as “continuous monitoring” and “home environments”, than the predicate device, such indications reduction do not raise different questions of safety or effectiveness, because the use environment for the proposed device is a subset of the use environment of the predicate device and the proposed device still maintains the core function as the oximeter, spot-check of non-invasive oxygen saturation of arterial hemoglobin (SpO2), and which has been validated by the non-clinical tests conducted.

Analyse 2：The SpO2 accuracy of proposed device is lower than predicate device. However it meets the requirements of ISO 80601-2-61, which FDA recognizes. Therefore, this difference is considered to not raise different questions of safety or effectiveness.

Analyse 3：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, this difference is considered to not raise different questions of safety or effectiveness.

Analyse 4: Although the Power supply specifications of of the proposed device is different from the predicate device,but both the predicate device and the proposed device have passed the IEC60601-1 standard; we believe these differences will not raise different questions of the effectiveness and safety compared with the predicate device.

Analyse 5: The proposed device and predicate device has different receiver terminal, Smart Phone VS PC, we have conducted the Wireless Coexistence Test and the results shown that the different receiver terminal will not raise different questions of the effectiveness and safety.

The proposed device and predicate device has different in wireless communication functions, but all such functions of proposed device are covered by predicate’s, so we believe these differences will not raise different questions of the effectiveness and safety compared with the predicate device.

9. Substantially Equivalent (SE) Conclusion

The clinical and non-clinical data support that the proposed device is as safe and as effective as the predicate device and does meet its design specification, and which are comparable to the predicate device. Also, the differences in the technological characteristics have been demonstrated to be substantially equivalent and thus the subject device is considered substantially equivalent to the predicate device.