DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 8, 2017

Xuzhou Yongkang Electronic Science Technology Co., Ltd
% Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, Dafangju, No.25 Banbidian Rd.
Li Yuan Town, Tongzhou District, Beijing, 101121
CHINA

Re: K161938
Trade/Device Name: Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 26, 2017
Received: March 30, 2017

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.

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,

Tina Kiang
-S

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)*

K161938

Device Name
Fingertip Pulse Oximeter

Indications for Use *(Describe)*
The pulse oximeter (YK-81C) is designed for spot checking of the pulse oxygen saturation and pulse rate for adult and pediatric 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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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: K161938

1. Date of Preparation

   03/27/2017

2. Sponsor

Xuzhou Yongkang Electronic Science Technology Co., Ltd

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3. Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Fingertip Pulse Oximeter
Common Name: Pulse Oximeter
Model(s): YK-81C

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, YK-81C, 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. Device Description

The proposed device, fingertip pulse oximeter, YK-81C, can display SpO2%, pulse rate value, and vertical bar graph pulse amplitude;

The pulse oximeter, YK-81C, is designed for spot checking of the pulse oxygen saturation and pulse rate for adults in a clinic environment. This medical device can be reused. Not for continuously monitoring.

The proposed device is NOT for life-supporting or life-sustaining, not for implant.
The proposed device is NOT provided sterile and is NOT a reprocessed single-use device.

6. Identification of Predicate Device

Predicate 1#
510(k) Number: K142687
Product Name: Pulse Oximeter
Manufacturer: Shanghai Berry Electronic Tech Co., Ltd.

Predicate 2#
510(k) Number: K093757
Product Name: MD300C1 Fingertip pulse oximeter
Manufacturer: Beijing Choice Electronic Technology Co., Ltd

7. 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:

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.
IEC 60601-1-8:2012 Medical electrical equipment General requirements for safety – for collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
Performance Test: SpO2 and PR accuracy/SpO2 and PR accuracy under low perfusion/SpO2 and PR accuracy test after cleaning and low-level disinfection (500 times)
Performance Test: Vertical Pulse Amplitude feature.
Performance Test: Finger Off and Low Battery indicator.

8. 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 YK-80C

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 21-28yr, 46-74kg, 156-176cm, with light to dark pigmentation) were included in the study conducted Nov. 27-29, 2015 to evaluate the SpO2 accuracy performance of proposed devices.

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 fingertip pulse oximeter to have an Arms of 2.53 (YK-81C) during steady state conditions over the range of 70-100%.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device Fingertip Pulse Oximeter (YK-81C)	Predicate Device Pulse Oximeter (BM1000A & BM2000A)	Predicate Device MD300C1 Fingertip pulse oximeter
Product Code	DQA	DQA	DQA
Regulation No.	21 CFR 870.2700	21 CFR 870.2700	21 CFR 870.2700
Class	2	2	2
Indications For Use	The pulse oximeter (YK-81C) 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 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.	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.
Application Site	Fingertip	Fingertip	Fingertip

Table 2 Performance Comparison

ITEM		Proposed Device Fingertip Pulse Oximeter (YK-81C)	Predicate Device Pulse Oximeter (BM1000A & BM2000A)	Predicate Device MD300C1 Fingertip pulse oximeter
Measurement wavelength		Red: 660nm Infrared: 940nm	Red: 660nm Infrared: 940nm	Red: 660nm Infrared: 940nm
LED Radiant Power		21.8 mW/cm^2	N/A	21.8 mW/cm^2
SpO2 Indication Waveform		Yes	Yes	Yes
SpO_2measurement range		0-100%	0-100%	0-100%
SpO_2accuracy		70%~100%, ±3%	70%-100% ±3%; Undefined for <70%	70%~99%, ±3%
SpO_2resolution		±1%	±1%	1%
PR measurement range		30-254 bpm	25-250 bpm	30~235bpm
PR accuracy		±2 bpm	±2 bpm	±2 bpm or ±2%
PR resolution		±1 bpm	±1 bpm	1bpm
Vertivcal bar graph pulse amplitude		The Pulse bar graph displays corresponding with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength as defined as below 0-15 level 9 block display in horizontal display mode (one block = 3/5 level) 15 block display in vertical display mode (one block = 1 level)	N/A	The Pulse bar graph displays corresponding with the patient's pulse beat. The height of the bar graph shows the patient's pulse strength.
Data update time		<10s	<15s	<15s
Technical Characteristics	Device Form	Finger clip Pulse Oximeter with built-in sensor	Handheld Pulse Oximeter with separate sensor	Finger clip Pulse Oximeter with built-in sensor
	Sensor type	Clip type	BM1000A: wrap type BM2000A: Fingertip type	Clip type

	Display Information	SpO2 measurement data PR measurement data Battery and finger off indicator SpO2/PR alarm setting	SpO2 measurement data PR measurement data Battery and finger off indicator SpO2/PR alarm setting (BM1000A only)	SpO2 measurement data PR measurement data Battery and finger off indicator SpO2/PR alarm setting

Table 3 Testing Comparison

ITEM	Proposed Device Fingertip Pulse Oximeter (YK-81C)	Predicate Device Pulse Oximeter (BM1000A & BM2000A)	Predicate Device MD300C1 Fingertip pulse oximeter
Power Supplier	2 A AA alkaline batteries	BM1000A: 2AA Batteries BM2000A: Li ion battery	2 A AA alkaline batteries
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Comply with ISO 10993-1
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements
Level of Concern of the Software	Moderate	Moderate	Moderate

The indications for use of the proposed device is identical to K142687, but varies slightly compared to K093757,However, they have same intended population, same usage environments, same intended use (spot checking and not for continuously monitoring), the only difference is the narrative style. These differences do not affect the safety and effectiveness of the device when used as labeled.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.