Beijing Safe Heart Technology Ltd.
Xiaoming Yang
Quality Manager
Room 101, Unit 6, Building NO.6
No.88 Kechuang 6th Street
Beijing Economic-Technological Development Area, 101111 Cn

Re: K172616
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: June 29, 2018
Received: June 29, 2018

Dear Xiaoming Yang:

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 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,

Todd D. Courtney -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)*
K172616

Device Name
PULSE OXIMETER

Indications for Use *(Describe)*
PULSE OXIMETER SHO-3002,SHO-3006 and SHO-3008 is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult at hospital (including clinical use internist/surgery, Anesthesia etc).It is 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.

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Section 6 - 510(k) Summary

Date of Summary Preparation: 06/21/2018

1. Submitter's Identifications

Submitter's Name: Beijing Safe Heart Technology Ltd.
Address: Room 101, Unit 6, Building NO.6, No.88 Kechuang 6th Street,Beijing Economic-Technological Development Area, 101111 Beijing, P. R. China
Contact Person: Mr. Xiaoming Yang
Contact Email Address: Email: QA@safeheart.com.cn
Phone number: +86- 10-61253661
Fax number: +86- 10-61253660-897

2. Correspondent’s Identifications

Submitter's Name: Beijing Safe Heart Technology Ltd.
Address: Room 101, Unit 6, Building NO.6, No.88 Kechuang 6th Street, Beijing Economic-Technological Development Area, 101111 Beijing, P. R. China
Contact Person: Mr. Xiaoming Yang
Contact Email Address: Email: QA@safeheart.com.cn
Phone number: +86-10-61253661
Fax number: +86-10-61253660-897

3. Name of the Device

Device Classification Name: Oximeter
Product Name: Pulse Oximeter
Trade Name: Pulse Oximeter
Model :SHO-3002，SHO-3006，SHO-3008
Classification Panel: Cardiovascular
Product Code: DQA
Device Classification: Class Ⅱ

4. The Predicate Devices

K130947	MD300C1,MD300C2 Fingertip pulse Oximeter	21 CFR 870.2700

5. Device Description

The devices consist of detector and emitter LED, CPU, display unit and power unit.
The Pulse oximeter is a kind of innovated medical detection device with non-invasive and continuous features for arterial SPO2 and PR detection. The proposed device consists of photo detector and emitter, LED, CPU, data display unit and power unit. It is portable and easy to measure the SPO2 and PR value quickly and precisely.
The series of pulse oximeter detect the body's oxygen saturation and pulse rate through the fingers.
The device does not contain drug or biological products.

The power sources of the proposed devices are 2 AAA alkaline batteries. All the proposed devices have low battery voltage indicator function, and all the proposed devices will automatically power off when there is no signal for longer than 5 seconds.

The proposed devices are not for life-supporting or life-sustaining, not for implant. The devices or transducers are not sterile and the transducers are reusable and do not need sterilization or re-sterilization. The devices are for prescription. The devices do not contain drug or biological products.

The Pulse oximeter SHO-3002, SHO-3006 and SHO-3008 share the same measurement principle and oximeter sensor and oxygen saturation module and power supply. The indented target population and use environment of the Pulse oximeter SHO-3002，SHO-3006 and SHO-3008 are the same.

The devices are software-driven and the software validation is provided in Section of Software.

6. Principle of operation and mechanism of action of the device

The device works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The wavelength of one light source is 660nm, which is red light; the other is 905nm, which is infrared light.

A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones.

Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.

7. Intended Use of Device

PULSE OXIMETER SHO-3002, SHO-3006 and SHO-3008 is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult at hospital (including clinical use internist/surgery, Anesthesia etc). It is not for continuously monitoring.

8. Summary of Substantial Equivalence

Table 1: The difference between SHO-3002, SHO-3006 and SHO-3008.

		SHO-3002	**SHO-3006**	**SHO-3008**
Display Range	Spo2	35%～100%	35%～100%	35%～100%
	PR	30bpm～250bpm	30bpm～250bpm	30bpm～250bpm
Measurement Range	Spo2	35%～100%	35%～100%	35%～100%
	PR	30bpm～250bpm	30bpm～250bpm	30bpm～250bpm
Accuracy	Spo2	70%～100% : ±2%, 0～69%:unspecified	70%～100% : ±2%, 0～69%:unspecified	70%～100% : ±2%, 0～69%:unspecified
	PR	±2bpm	±2bpm	±2bpm
Resolution	Spo2	1%	1%	1%
	PR	1 bpm	1 bpm	1 bpm

Display Screen	OLED	OLED	OLED
Pulse waveform display	Y	Y	Y
Four direction display	Y	Y	Y
Dimension (L x W x H)	57mm x 31. 5mm x 30. 5mm	57mm x 31. 5mm x 30. 5mm	57mm x 31. 5mm x 30. 5mm
Appearances and color	Different	Different	Different
Structure and composition	The proposed device consists of photo detector and emitter LED, CPU, data display unit and power unit.	The proposed device consists of photo detector and emitter LED, CPU, data display unit and power unit.	The proposed device consists of photo detector and emitter LED, CPU, data display unit and power unit.
Operating style	Fingertip	Fingertip	Fingertip
Accessories	1. One lanyard 2. Two batteries 3. One user's manual	1. One lanyard 2. Two batteries 3. One user's manual	1. One lanyard 2. Two batteries 3. One user's manual

Table 2 : The difference between Proposed Device and Predicate Device

Comparison Elements	**Proposed Device**	**Predicate Device**	**Comparison**
Device Name	Pulse oximeter	Fingertip pulse Oximeter (K130947)	Similar
Model	SHO-3002,SHO-3006 and SHO-3008	MD300C1,MD300C2	------
Regulation No.	21 CFR 870.2700	21 CFR 870.2700	Same
Classification	II	II	Same
Classification Name	Oximeter	Oximeter	Same
Product Code	DQA	DQA	Same
Indications for Use	PULSE OXIMETER SHO-3002,SHO-3006 and SHO-3008 is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult at hospital (including clinical use internist/surgery, Anesthesia etc).It is not for continuously	The Fingertip Pulse Oximeter MD300C series, are portable, non-invasive devices intended for spot checking of arterial hemoglobin oxygen saturation(SPO2) and pulse rate of adult and pediatric patient at hospital (including	Similar

		monitoring.	clinical use in internist/surgery, Anesthesia, and intensive care units).	
Comparison Statement		The proposed devices have the same indications for use and classification.		
Components		The applicant device consists of photo detector and emitter LED, CPU, data display unit and power unit.	Detector and emitter LED, signal amplify unit, CPU, data display unit and power unit.	Similar
Design Principle		A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the Oximeter's display through process in electronic circuits and microprocessor shown on the Oximeter's display through electronic circuits and a microprocessor.	Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amount of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SPO2.	Similar
Measurement Wavelength	Red	660nm	660nm	Same
	Infrared	905nm	940nm	The wavelength of IR led is different. SE Note 1
Comparision Statement		The proposed devices have the same design principle and similar components.		
Display Type		OLED	LED:MD300C1	Same

			OLED:MD300C2	Same
Working time		Work about 30 hours continuously.	Work for 30 hours continuously	Same
Power Supply		2 * AAA	2 * AAA	Same
Display Data		SPO2, PR	SPO2, PR	Same
Spo2 Display Range		35%～100%	0~99%: MD300C1	Same
			0~100%: MD300C2	Same
Spo2 Accuracy		70%～100% : ±2%, 0～69% is no definition	MD300C1: 70~99% is ±2%, 0~69% is no definition	The Spo2 Display Range is different. SE Note 2
			MD300C2: 70~100% is ±2%, 0~69% is no definition	
Spo2 resolution		1%	1%	Same
PR display range		30～250bpm	0~254 bpm	The PR range of the predicate device is bigger. SE Note 3
PR Accuracy		±2bpm	±2bpm(30~99bpm) and 2%(100~235bpm)	Same
PR resolution		1 bpm	1 bpm	Same
Operating temperature		+5°~+40°C	+5°~+40°C	Same
Relative humidity		15%～90%(Operating), 15%～93%（Storage）	≤80%(Operating) ≤93%(storage)	Similar
Atmosphere pressure		860hPa～1060hPa (Operating) 500hPa-1060hPa (Storage)	86~106 kPa	Similar
Pulse Beep		Not Available	Not Available	Same
Comparison Statement		The applicant device has similar device specifications as the predicate device.		
Contacting Material	Battery cover	ABS	ABS	Same
	Fingertip Cushion	Medical Silica gel	Medical Silica gel	Same
	Enclosure	ABS	ABS	Same
Comparsion Statement		The contacting materials of applicant device are same as to the predicate device.		
Performance Testing	Bench Test	The bench test include SpO2 accuracy test， pulse rate test, FFC bending test, drop test, function test and test according to ISO80601-2-61.All the bench test results are provide in performance Testing-Bench	Meet the requirements of FDA Guidance.	Similar

	Clinical Test	Conformed to ISO80601-2-61		Conformed to ISO 9919		Similar
Electromagnetic Compatibility Safety	Electrical Safety	Conformed to IEC60601-1. The test results are provided in Electromagnetic Compatibility and Electrical Safety.		Conformed to IEC60601-1		Same
	Electromagnetic Compatibility	Conformed to IEC60601-1-2. The test results are provided in Electromagnetic Compatibility and Electrical Safety.		Conformed to IEC60601-1-2		Same
Software		Moderate level of Concern		Moderate level of Concern		Same
		Compliance with FDA Guidance for the content of Premarket Submissions for Software Contained in Medical Devices.		Compliance with FDA Guidance for the content of Premarket Submissions for Software Contained in Medical Devices.		Same
Biocompatibility	Medical Silica gel	In Vitro Cytotoxicity	No cytotoxic potential	In Vitro Cytotoxicity	No cytotoxic potential	Same
		Skin Irritation Test	No evidence of causing sensitization	Skin Irritation Test	No evidence of causing sensitization	Same
		Skin Sensitization Test	No evidence of significant irritation from the test extract to rabbits	Skin Sensitization Test	No evidence of significant irritation from the test extract to rabbits	Same
Label and Labeling		Compliance with FDA guidance		Compliance with FDA guidance		Similar

9. Substantial Equivalence:

SE Note 1:

The degree of light absorption and the degree of light scattering of blood are mainly related to the content of oxygenated hemoglobin, which is feasible in the infrared spectrum area (800nm ~ 1000nm). Although the “Measurement Wavelength” of the subject device is slightly different from the predicate device ,all devices comply with infrared spectrum area (800nm ~ 1000nm), ES 60601-1 and ISO80601-2-61 requirements. These differences do not raise different questions of safety and effectiveness.

SE Note 2:

When the human blood oxygen saturation value less than 60%, the non-invasive blood oxygen error will be

relatively large. So, non-invasive blood oxygen products will be specified in the Spo2 Accuracy measurement, 0 ~ 69% interval is not definition. Although the “Spo2 Display Range” of the subject device is slightly different from the predicate device, all devices comply with clinical application, ES60601-1 and ISO80601-2-61 requirements. These differences do not raise different questions of safety and effectiveness.

SE Note 3:

Clinical experience show that range of the pulse rate interval 30bpm ~ 250bpm, has been able to meet the clinical application. Although the “PR Display Range” of the subject device is slightly different from the predicate device ,all devices comply with clinical application, ES60601-1 and ISO80601-2-61 requirements. These differences do not raise different questions of safety and effectiveness.

According to the non-clinical and clinical test results, the proposed devices are as safe, as effective and perform as well as the predicate device. So, the proposed devices are Substantially Equivalent (SE) to the predicate device which is US legally market device.

10. Non-Clinical Tests Performed:

The following testing was performed on the Pulse Oximeter SHO-3002, SHO-3006 and SHO-3008 in accordance with the requirements of the design control regulations and established quality assurance procedures.

a. ES60601-1:2005/(R) 2012, Medical electrical equipment-Part 1: General requirements for basic safety, and essential performance.

b. IEC60601-1-2:2014, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility-Requirements and tests.

c. ISO80601-2-61:2011, Medical electrical equipment-Part 2-6 1: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

d. ISO10993-1:2009, Biological evaluation of medical devices -Part 1:Evaluation and testing within a risk management process

e. ISO10993-5:2009, Biological evaluation of medical devices - PartS5: Tests for In Vitro cytotoxicity.

f. ISO10993-10:2010, Biological evaluation of medical devices-Part10: Tests for irritation and skin sensitization

g. Software Validation and Verification Test.

h. Use Life Test.

i. SpO2 Accuracy and Pulse Rate Accuracy Test (Test after the repeated clean & disinfection conditions).

j. SpO2 Accuracy and Pulse Rate Accuracy Test (Test under the normal conditions).

k. SpO2 Accuracy and Pulse Rate Accuracy Test (Test under the low perfusion conditions).

l. Storage Condition Test

11. Summary of the biocompatibility tests performed on the device.

Direct contacting the skin components included Plastic Shell (ABS Novodur HD M203FC） and color additives（BASF K7090，BASF L0080）, Silica gel pad (Medical grade silica gel HCRU4470) and color additives（SUNWELL SILICONES P801. Plastic Shell included ABS and color additives, Silica gel pad included medical grade silica gel and color additives were tested together. Because the material only contact with the user's intact skin within 24 hours, so according to ISO 10993-1:2009, the In Vitro Cytotoxicity Test, Skin Sensitization Test and Skin Irritation Test have been performed.

12. Clinical Trial Conclusion

The Pulse Oximeter SHO-3002, SHO-3006 and SHO-3008 share the same pulse oximeter sensor, algorithm and oxygen saturation module. So, we considered a clinical test of one of the proposed devices could cover that of other devices. The clinical test of other proposed devices can be exempted. And we conducted clinical test for one of the proposed devices, and the model is SHO-3002.

The clinical trial was performed according to Annex EE.2 Procedure for invasive laboratory testing of ISO80601-2-61:2011, Medical electrical equipment-Part 2-6 1: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

It can be determined from the result of the clinical study that the accuracy Arms of the proposed device is smaller than 2%.

13. Substantially Equivalent Conclusion

The proposed device Pulse Oximeter SHO-3002, SHO-3006 and SHO-3008 are determined to be Substantially Equivalent (SE) to the predicate device, Fingertip Pulse Oximeter (K130947) MD300C1, MD300C2.