DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 4, 2014

Hunan Accurate Bio-Medical Technology Company Limited
Mr. Li Zhang
Quality Manager
M8-613, No. 8, Lutian Road
Changsha National Hi-Tech Industrial Development Zone
Changsha, Hunan 410205
CHINA

Re: K141105
Trade/Device Name: Pulse Oximeter, Model FS10A and FS20A
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 5, 2014
Received: November 5, 2014

Dear Mr. Zhang:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141105

Device Name

Pulse Oximeter

Indications for Use *(Describe)*

The Pulse Oximeter FS10A and FS20A are portable, non-invasive devices intended for spot check monitoring of arterial hemoglobin oxygen saturation (SpO2) and pulse rate of adult patients (weighing ≥ 30 kg) in hospitals.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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Section 6 - 510(k) Summary

Date of Summary Preparation: 12/04/2014

1. Submitter's Identifications

Submitter's Name: Hunan Accurate Bio-Medical Technology Co., Ltd.
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2. Correspondent's Identifications

Submitter's Name: Hunan Accurate Bio-Medical Technology Co., Ltd.
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3. Name of the Device

Device Classification Name: Oximeter
Product Name: Pulse Oximeter
Trade Name: Pulse Oximeter
Model: FS10A,FS20A
Classification Panel: Cardiovascular
Product Code: DQA
Device Classification: Class Ⅱ

4. The Predicate Devices

K139047.	MD300C1,MD300C2 Fingertip pulse Oximeter	21 CFR 870.2700

5. Device Description

The proposed devices of Pulse Oximeter FS10A, FS20A are fingertip devices, which can display SpO2 and pulse rate value. The proposed devices consist of detector and emitter LED, CPU, display unit and power unit.

The pulse oximeter 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 660 nm, which is red light; the other is 906nm, which is infrared light.

Skin, bone, tissue, and venous vessels normally absorb a constant amount of light overtime. The photodetector 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 amounts 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.

The power sources of the proposed devices are 2 AAA alkaline batteries. All of the proposed devices have low battery voltage indicator function and all of the proposed devices will automatically power off when there is no signal for longer than 8 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 Oximeters FS10A,FS20A 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 Oximeters FS10A, FS20A are the same.

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

6. Intended Use of Device

The Pulse Oximeter FS10A and FS20A are portable, non-invasive devices intended for spot check monitoring of arterial hemoglobin oxygen saturation (SpO2) and pulse rate of adult patients (weighing ≥ 30 kg) in hospitals.

7. Summary of Substantial Equivalence

Table 1: The difference between FS10A and FS20A.

		FS10A	**FS20A**
Display Range	Spo2	0~99%	0~100%
	PR	0~250 bpm	0~250 bpm
Measurement Range	Spo2	70~99%	70~100%
	PR	25~250	25~250
Accuracy	Spo2	70~99%：±2% 0%~69%: no definition	70~100%：±2% 0%~69%: no definition
	PR	±3 bpm	±3 bpm
Resolution	Spo2	1%	1%

	PR	1 bpm	1 bpm
Display Screen		LED	OLED
Pulse Beep		N	Y
Pulse beat sound		N	Y
Pulse sound On/Off function		N	Y
Pulse waveform display		N	Y
Four direction display		N	Y
The shape and size of shell		The proposed devices have the same appearances and sizes.	

Table 2 : The difference between FS10A,FS20A and Predicate

Compariosn Elements	**Proposed Device**	**Predicate Device**	**Comparison**
Device Name	Pulse oximeter	Fingertip pulse Oximeter (K130947)	Similar
Model	FS10A, FS20A	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	The Pulse Oximeter FS10A and FS20A are portable, non-invasive devices intended for spot check monitoring of arterial hemoglobin oxygen saturation (SpO2) and pulse rate of adult patients (weighing ≥ 30 kg) in hospitals.	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 clinical use in internist/surgery, Anesthesia, and intensive care units).	Similar
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	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	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	Similar

		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.	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.	
Measurement Wavelength	Red	660nm	660nm	Same
	Infrared	906nm	940nm	The wavelength of IR led is different.
Comparision Statement		The proposed devices have the same design principle and similar components.		
Display Type		LED: FS10A	LED:MD300C1	Same
		OLED:FS20A	OLED:MD300C2	Same
Working time		Work about 18 hours continuously.	Work for 30 hours continuously	
Power Supply		2 * AAA	2 * AAA	Same
Display Data		SPO2, PR	SPO2, PR	Same
Spo2 Display Range		0~99%: FS10A	0~99%: MD300C1	Same
		0~100%: FS20A	0~100%: MD300C2	Same
Spo2 Accuracy		FS10A: 70~99% is ± 2%, 0~69% is no definition	MD300C1: 70~99% is ± 2%, 0~69% is no definition	Same
		FS20A: 70~100% is ± 2%, 0~69% is no definition	MD300C2: 70~100% is ± 2%, 0~69% is no definition	Same
Spo2 resolution		1%	1%	Same
PR display range		0~250 bpm	0~254 bpm	The PR range of the predicate device is bigger.
PR Accuracy		±3bpm	± 2bpm(30~99bpm) and 2%(100~235bpm)	The PR accuracy of the predicate device is higher.
PR resolution		1 bpm	1 bpm	Same
Operating temperature		+5° ~+40° C	+5° ~+40° C	Same

Relative humidity		10%~95%(Operating and storage)	≤80%(Operating) ≤93%(storage)	Similar
Atmosphere pressure		70~106kPa (Operating) 50~107.4kPa(Storage)	86~106 kPa	Similar
Pulse Beep		Available: FS20A Not Available: FS10A	Not Available	The predicate device doesn't have the Beep function.
Comparison Statement		The applicant device has similar device specifications as the predicate device.		
Contacting Material	Battery cover	ABS + PC	ABS	Similar
	Fingertip Cushion	Medical Silicon gel	Medical Silicon gel	Same
	Enclosure	ABS + PC /PMMA	ABS	Similar
Comparsion Statement		The contacting materials of applicant device are similar to that of 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 Clinical test for device accuracy is conducted by the Guangzhou Huangpu Traditional Chinese Medicine Hospital. The clinical test report and protocol are provide in performance Testing-clinical	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 Silicone 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
	ABS + PC /PMMA plastic	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

8. Substantial Equivalence:

The proposed devices of Pulse Oximeter FS10A, FS20A have the same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance effectiveness, performance safety as the predicate device.

The differences only exist in such contents: Infrared wave length, PR display range and accuracy and Pulse Beep function. These differences are slight and do not influence the effectiveness and safety of the device.

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.

9. Non-Clinical Tests Performed:

The following testing was performed on the Pulse Oximeter FS10A,FS20A in accordance with the requirements of the design control regulations and established quality assurance procedures.

IEC60601-1:2005+CORR.1(2006)+CORR.2(2007),Medical electrical equipment-Part 1:General requirements for basic safety, and essential performance.
IEC60601-1-2:2007, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility-Requirements and tests.
ISO80601-2-61:2011, Medical electrical equipment-Part 2-6 1: Particular requirements for basic safety and essential performance of pulse oximeter equipment.
ISO10993-1: 2009, Biological evaluation of medical devices -Part 1:Evaluation and testing within a risk management process
ISO10993-5:2009, Biological evaluation of medical devices - PartS5: Tests for In Vitro cytotoxicity.
ISO10993-10:2010, Biological evaluation of medical devices-Part10: Tests for irritation and skin sensitization
In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

10. Clinical Trial Conclusion

The Pulse Oximeters FS10A and FS20A 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 FS20A.
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%.

11. Substantially Equivalent Conclusion

The proposed device Pulse Oximeter FS10A,FS20A are determined to be Substantially Equivalent (SE) to the predicate device, Fingertip Pulse Oximeter (K130947) MD300C1,MD300C2 in respect of safety and effectiveness.

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