March 27, 2018

Hunan Accurate Bio-Medical Technology Co., Ltd.
Zhou Le
RA Manager
M8-613, No.8, Lutian Road, Changsha National
Hi-Tech Industrial Development
Changsha, 410208 CN

Re: K171241
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: February 2, 2018
Received: February 23, 2018

Dear Zhou Le:

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)*

K171241

Device Name

Pulse Oximeter

Indications for Use *(Describe)*

The pulse oximeter is indicated for continuous or spot check monitoring of functional arterial oxygen saturation (SpO2) and pulse rate of adult patients in hospitals and clinics.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5 510(K) Summary

Prepared Date: 2018/1/31

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

There is no prior submission for the device.

Submitter Information

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Phone number: +86- 731-89745029 Fax number: +86- 731-89745029

Contact person: Zhou Le

E-mail: regulation@accbiomed.com

Name of device

Trade name: Pulse Oximeter Models: HS10A

Classification name: Oximeter

Production regulation: 21CFR 870.2700

Product code: DQA

Classification Panel: Cardiovascular

Device Classification: Class2

Predicate Device

OxiMaX™ NPB-40 Pulse Oxirneter (K051352, Nelicor Pui-itan Bennett)

Description

The HS10A is a handheld, battery powered pulse oximeter used for monitoring of pulse rate and functional arterial oxygen saturation in arterial blood. The HS10A include the addition of audible alarms, addition of keys and display icons in the user interface board to access the alarm settings.The device also has menu features to allow the user to set the time, date and measurement alarm limits.

Intended use

The pulse oximeter is indicated for continuous or spot check monitoring of functional arterial oxygen saturation (SpO2) and pulse rate of adult patients in hospitals and clinics.

Substantially Equivalent

A comparison of key similarities and differences between the subject device (Model HS10A) and the predicate devices (K051352) is provided below.

Item	HS10A Subject device	OxiMaXTM NPB-40 Predicate device	Comment
Intended use &indications for use	The handheld pulse oximeter is indicated for continuous or spot check monitoring of functional arterial oxygen saturation (SpO2) and pulse rate of adult patients in hospitals and clinics.	The OxiMaxTM NPB-40 handheld pulse oximeter is indicated for continuous or spot check monitoring of functional arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric and neonatal patients in hospital, hospital type facilities, transport and mobile environments as well as in the home care environment.	Similar
Prescriptive	Prescription Use	Prescription Use	Same
Measurement place	Finger	Finger or toes	Similar
Operation Principle	The Pulse Oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. Skin,bone, tissue, and venous normally absorb a constant 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.	The NPB-40 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an OXIMAX sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The OXIMAX sensor contains a dual light source and a photo detector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable mounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2).	Same
Display	LCD	LCD	Same
Power supply	3*1.5 V, AA	4*1.5 V, AA	-----

Display range	SPO2:1-100% PR:25-300bpm	SPO2:1-100% PR: 20-300bpm	Similar
SpO2 measurement range& accuracy	70-100% no less than ±2%(No motion)	70-100% no less than ±2%(No motion) 70-100% no less than ±3%(motion) 70-100% no less than ±2%(Low Perfusion)	Similar
PR measurement range& accuracy	25—250 bpm no less than ±3 bpm (No motion)	20-250bpm no less than ±3 bpm(No motion) 55-125 bpm on less than±5bpm(motion) 20-250bpm no less than ±3 bpm(Low perfusion)	Similar
Perfusion range	No	0.03%-20%	Similar
Display Resolution	SPO2:1%,PR:1bpm	SPO2:1%,PR:1bpm	Same
Alarm type	visual alarm and information	visual alarm and information	Same
Alarm limit range	SPO2 high limit:low limit +1 to 100% SpO2 low limit:20% to (high limit-1) PR high limit:(low limit+1) to 250 PR low limit: 30 to (high limit-1)	SPO2 high limit:low limit +1 to 100% SpO2 low limit:20% to (high limit-1) PR high limit:(low limit+1) to 170 PR low limit:30 to (high limit-1)	Similar
Default limit	SPO2: High 100%,Low 90% PR: High 90 bpm,Low 40bpm	SPO2: High 100%,Low 85% PR: High 170bpm, Low 40bpm	Similar
Memory	No	Yes	Similar
Buzzer	Yes	Yes	Same
Auto power-off	Yes	Yes	Same
Operating Environment	Temperature：5℃～+40℃ Humidity： 15% ～ 95% non-condensing	Temperature：5℃～+40℃ Humidity： 15% ～ 95% non-condensing	Same
Storage Environment	Temperature：-20℃～+60℃; Humidity： 15% ～ 95% non-condensing	Temperature：-20℃～+60℃; Humidity： 15% ～ 95% non-condensing	Same
Weight	300g	280g	---
Size	56×124×30 mm	73X159X35mm	---
Conformance standard	IEC60601-1 IEC60601-1-2	IEC60601-1 IEC60601-1-2	Same

	ISO10993-5/-10 ISO80601-2-61	ISO10993-5/-10 ISO80601-2-61	

From the comparison form above, the subject device and predicate device have similar intended use, are both prescription use, and have the same Operation Principle, Display screen, Conformance to standard. The subject device claims slightly different patient population & use environment, measurement site and technology parameter. But the subject device met the requirements of IEC60601-1, IEC60601-1-2, ISO80601-2-61and IFU, so these differences between subject device and predicate device do not raise different questions of safety or effectiveness issues since the intended use is a subset of the predicate's intended use.

Non-clinical Performance Data

The following practices were followed and monitored for development of the Digital blood pressure monitor:

- IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety, 2005
- IEC 60601-1-2 Medical Electrical Equipment-Part 1-2: General Requirements for Safety -Collateral Standard: Electromagnetic Compatibility-Requirements and Tests, 2007
- ISO 80601-2-61:2011 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 10993-1, Biological evaluation of medical devices-Part 1: Evaluation and testing, 2009
- ISO 10993-5, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity, 2010

Clinical Performance Data

The pulse oximeter was subjected to clinical testing. The functional oxygen saturation (SpO2) measurement has been validated in accordance with ISO 80601-2-61. The clinical testing was completed on a total of 12 healthy adult male and female volunteers (with a total of 300 blood samples) with light to dark skin pigmentations in the range of 70% to 100% against a laboratory CO-Oximeter. The SpO2 accuracy results include:

- 1.391% which meets the accuracy requirement of less than or equal to 2% under no motion condition.

The accuracy specification is reported as accuracy root mean square (Arms).

Conclusion

The non-clinical and clinical testing provided in this 510(k) submission demonstrates that the subject device, the Pulse Oximeter, is as safe and as effective, and substantially equivalent to the predicate device.