DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 18, 2016

Shenzhen Medke Technology Co., Ltd
Lao Chengxin
General Manager
4/F, Bldg. A1, Anle Ind. Zone, Hangcheng RD., Baoan Dist.
Shenzhen , China 518126

Re: K152390
Trade/Device Name: Medke Oximetry Finger Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 15, 2016
Received: July 20, 2016

Dear Lao Chengxin:

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 yours,

James J. Lee -S

Digitally signed by James J. Lee -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=James J. Lee -S, 0.9.2342.19200300.100.1.1=2000954859
Date: 2016.08.18 17:22:19 -04'00'

For Tina Kiang, PhD
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)*

Device Name
Medke Oximetry Finger Sensor

Indications for Use *(Describe)*
Medke Oximetry Finger Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate(PR) for adult patients weighing greater than 40kg.

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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Section 5 510(K) Summary

1. Prepared Date: 2016-8-16

2. Submitter Information

Name	Shenzhen Medke Technology Co.,LTD
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3. Contact Person

Contact person	LAO CHENGXIN
Title	General Manager
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Tel	0086-755-23463462
Fax	0086-755-29553084
E-mail	info@medke.com

4. Proposed Device Information

Trade Name	Medke Oximetry Finger Sensor
Model	P9119& P8119
Common name	Oximeter
Regulatory class	II
Production regulation	21 CFR §870.2700
Product code	DQA
Panel	Cardiovascular

5. Predicate Device Information

510(K)No.	Trade Name/model	Submitter
K100077	Solaris Medical Technology, Inc. Reusable & Disposable SPO2 Sensors	Solaris Medical Technology, Inc.

6. Device description

The Medke Oximetry Finger Sensors are compatible sensor for use with major types of patient monitors and oximeter devices of Original Equipment Manufacturer (OEM).

The sensors are made up of connector, cable, two specific wavelength LEDs & a photo detector assembled into the sensor housing. The sensors use optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter.

The Medke Oximetry Finger Sensors contain finger clip type and soft tip type. The finger clip sensor is comprised of a plastic shell with silicone pads which position the optical components, and a cable with OEM compatible connector. The soft finger sensor consists of an integrated silicone rubber tip which is installed the optical components, and a cable with OEM compatible connector.

The Medke Oximetry Finger Sensors have unique labeling and specifications designed for compatibility with Nellcor patient monitor(NPB40) cleared in K963707.

7. Intended use

Medke Oximetry Finger Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate(PR) for adult patients weighing greater than 40kg.

8. Comparison to predicate device

The Medke Oximetry Finger Sensors utilize the same measurement principles as the listed predicate devices: two wavelengths of light (red, infrared) from light emitting diodes (LED's) illuminate the patients arterial tissue; and the light transmission through the tissue is measured using a photodiode light detector. The transmission properties vary with the patient's arterial blood saturation and pulse rate.This method is fundamental to all pulse oximeter sensors and monitors for the non-invasive measurement of functional oxygen saturation (SpO2). Please see the comparison list:

Comparison item	Subject Device Medke Oximetry Finger Sensor (Model: P9119& P8119)	Predicate Device Reusable and disposable SPO2 sensor compatibility with Nellcor (model:T100A-090103 soft sensor) K100077	Note
Intended use& Indications for Use	Medke Oximetry Finger Sensor are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate(PR) for adult	When used with a compatible patient monitor or a pulse oximeter device, Solaris Medical Technology, Inc. reusable & disposable SpO2 sensors are intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO2) and pulse rate monitoring. Solaris Medical Technology, Inc. reusable	same

	patients weighing greater than40kg,.	multi-patient use SpO2 Soft Sensors, reusable multi-patient use SpO2 Finger Sensors, and disposable single patient use SpO2 Soft-finger Sensors are for use with adult/pedliatric patients weighing greater than 40kg. Solaris Medical Technology, Inc. disposable single patient use SpO2 Adhesive Sensors are for use with adult patients weighing greater than 40kg, pediatric patients weighing 10 - 40 kg, and infant (non-neonatal) patients weighing 3 - 15kg. Prescription device.	
Measurement Method	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	Same
Light Emitting	Red:660-666nm, Ired:880-950nm	Red:660-666nm, Ired:880-950nm	same
Signal Detection Method	Photodetector	Photodetector	Same
SPO2 Accuracy	±3%(70-100%)	±2%(70-100%)	Similar
Pulse Rate Accuracy	±3(30-250bpm)	±2(30-250bpm)	Simiar
Applied population	Adult(≥40Kg)	Adult(≥40Kg)	same
Measurement part	Fingers or toes	Fingers or toes	Same
compatible monitor	Nellcor(N395)	Nellcor(N395)	Same
Sterility	No	No	Same
Usage	Reusable	Reusable	Same
Material	ABS,PVC,TPU,Silicone	ABS,PVC,Silicone	Similar
Cable Length	1.0	0.9	Similar
Proximal connector Design	DB9 9pin	DB9 7pin	Similar
Distal connector Design	finger clip , soft tip,	soft tip	Similar
Conformance standard	IEC60601-1,IEC60601-1-2,ISO80601-2-61,ISO	IEC60601-1,IEC60601-1-2,ISO80601-2-61,ISO10993-5/10	Same

	10993-5/10		

From the comparison form above, both devices have the same Measurement Method, Light Emitting, Signal Detection Method , Measurement part , compatible monitor , Sterility, Usage & Conformance standard.

Regarding SPO2 & Pulse Rate Accuracy, Material, Distal connector design, both devices have some difference, but the subject devices have passed the ISO80601-2-61, IEC60601-1,IEC60601-1-2,and ISO10993-5/10 testing.

According to contrast and analysis, So, the differences between subject device and predicate device do not raise different questions of safety or effectiveness.

9. Non-clinical test data

The subject device meets the following the recognized standards:

- 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 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- 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

10. Clinical data summary

1) SPO2 Accuracy

According to IEC80601-2-61, Invasive "breathe-down" test refers to compare SpO2 which was measured from subject devices and CO-Oximeter of measured standard arterial blood SaO2, that is, through comparing and observing the SpO2 which was obtained from five oxygen saturation stable stages by inhaling different FiO2 by volunteers and SaO2 which was measured by extract radial artery blood sample periodically through arterial duct on a group of healthy adult volunteers within the scope of the oximeter accuracy specification.

12 healthy adults were selected as subjects for this accuracy trial. One subject can acquired 25 data samples, and 300 data pairs were obtained. Compare and analyze these data pairs (SPO2VSSaO2), the result is as follows:

Table 1 SPO2 Accuracy

Model	Monitor	Root Mean Square(Arms)							
		60-79	80-100	60-100	70-100	60-69	70-79	80-89	90-100
P9119	NPB-40	1.57	1.31	1.39	1.37	2.6	1.52	1.38	1.26
P8119	NPB-40	1.61	1.31	1.40	1.39	1.62	1.61	1.38	1.24
Conclusion		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

2) PR Accuracy

Use the simulator with patient monitor(NPB40) to test the PR Accuracy in the range of 30-250BPM, the testing result is as follows:

Table 2 Pulse Rate Accuracy

Item	Sensor model	Monitor model	Arms	each level Arms				
			70-100	77-70	84-78	92-85	97-92	100-97
1	P9119	NBP-40	1.63	1.17	0.67	1.83	2.00	2.50
2	P8119	NBP-40	1.67	0.67	2.00	1.83	2.00	1.83
	Conclusion		Pass	Pass	Pass	Pass	Pass	Pass

From the test result above,the SPO2 accuracy of Medke Oximetry Finger Sensor (P9119&P8119) is 1.37~1.39 in range 70-100%, and the PR accuracy is 1.63~1.67 in range 30~250 BPM, which meets the requirements of ISO80601-2-61.

11. Substantial Equivalence Statement

Based on the comparison ,analysis, and the submitted performance data, Medke Oximetry Finger Sensors are as safe and effective and are substantially equivalent to the predicate devices.