DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 04, 2017

Shenzhen Caremed Medical Technology Co., Ltd.
Xinlin Xiao
QA Manager
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Longhua Office, Longhua New District
Shenzhen, Guangdong 518021
China

Re: K153184
Trade/Device Name: Caremed Reusable & Disposable SpO2 Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: June 13, 2016
Received: December 5, 2016

Dear Xinlin Xiao:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
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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)*
K153184

Device Name

Caremed Reusable & Disposable SPO2 Sensors

Indications for Use *(Describe)*

Caremed Reusable & Disposable SPO2 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 40 kg and pediatric patients weighing 10 -50 kg at hospital facilities

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: 2017/1/3

2. Submitter Information

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3. Contact Person

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4. Proposed Device Information

Trade Name	Caremed Reusable & Disposable SPO2 Sensors
Model	C403-01,C403S-15&N543-01
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.
K111888	Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors	Masimo Corporation

6. Device description

Caremed Reusable & Disposable SPO2 Sensors use optical means to determine the light absorption of functional arterial hemoglobin by being connected between the

patient and the patient monitor or oximeter device. The probe contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector. The LED and photodiode are contained in sensor housing.

Three models of sensors are described as follows:

Model	Description	Compatible Monitor
C403-01	Nellcor Adult Reusable Finger Clip SpO2 Sensor	N395
C403S-15	Masimo Adult Reusable Soft tip SpO2 Sensor	Masimo Radical Rad-8
N543-01	Nellcor Adult Disposable Non- Adhesive SpO2 Sensor	N395

7. Intended use

Caremed Reusable & Disposable SPO2 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 than40kg and pediatric patients weighing 10 -50 kg at hospital facilities.

8. Comparison to predicate device

Caremed Reusable & Disposable SPO2 Sensors use the same technological characteristics as the predicate devices to determine arterial oxygen saturation: arterially perfused tissue is illuminated sequentially by two wavelengths of LEDs, and the time varying absorbance of the tissue is measured by a photodetector.
Based on the following comparison, both device have same intended use,working principle ,measurement part,compatibility ,only in technical parameters and cable length have slightly difference. But the subject devices have passed IEC60601-1,IEC60601-1-2,ISO80601-2-61&performance testing, so these difference does not raise different questions of safety or effectiveness. Please see the following comparison table:
Table 1

Comparison item	Subject Device Caremed Reusable and disposable SPO2 sensor compatibility with Nellcor (Model:C403-01,C403S-15 &N543-01)	Predicate Device Reusable and disposable SPO2 sensor compatibility with Nellcor (model:T100A-090103 and DP100A-090103) K100077	Predicate Device Adult and pediatric/slender digit spo2 sensor (model: LNOP DCI series) K111888

Intended use& Indications for Use	Caremed Disposable and Reusable SPO2 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 than40kg and pediatric patients weighing 10 -50 kg	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 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/pediatric 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.	The Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SPO2) and pulse rate (measured by an SPO2 sensor) for use with adult, pediatric, infant, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.
Measurement Method	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption
Light Emitting	Red:660-666nm, Ired:880-950nm	Red:660-666nm, Ired:880-950nm	Red:660-666nm, Ired:880-950nm
Signal Detection Method	Photodetector	Photodetector	Photodetector
SPO2 Accuracy	±3%(70-100%)	±2%(70-100%)	±2%(70-100%)

Pulse Rate Accuracy	±3(30-250bpm)	±2(30-250bpm)	±3(30-250bpm)
Applied population	C403-01 & C403S-15: Adult(≥40Kg) N543-01: Adult(≥40Kg) & Pediatric(10-50Kg)	Adult(≥40Kg)	Adult(≥30Kg)
Measurement part	Fingers or toes	Fingers or toes	Fingers or toes
compatible monitor	Nellcor Non oximax (N395)& Masimo set	Nellcor Non oximax (N395)	Masimo set
Sterility	No	No	No
Usage	Reusable&disposable	Reusable&disposable	Reusable
Material	ABS,PVC,TPU,Silicone, sponge	ABS,PVC,Silicone and 3M	ABS,PVC,TPU,Silicone
Cable Length	1.1	0.9	0.9
Proximal connector Design	DB9 9pin&1269 LNOP DC	DB9 7pin	1269 LNOP DC
Distal connector Design	finger clip and sponge adhesive	soft tip and textile adhesive	finger clip
Conformance standard	IEC60601-1,IEC60601-1-2, ISO80601-2-61,ISO10993-5/10	IEC60601-1,IEC60601-1-2, ISO80601-2-61,ISO10993-5/10	IEC60601-1,IEC60601-1-2, ISO80601-2-61,ISO10993-5/10

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.

In Intended use& Indications for Use, SPO2 & Pulse Rate Accuracy, Applied population, Material item, both devices have some differences; please see the following analyses.

Note1 Intended use, Indications for Use& Applied population

The C403-01 is intended use for adult keeping still in in hospital environment which is same as predicate device T100A-090103. And the applied population of C403S-15 is adult with no motion which is slightly difference from the predicate device LNOP DCI series sensor. The N543-01 will be intended use for adult and Pediatric patients weighting 10-50Kg, which are same as the Nellcor(OEM) spo2 sensor. The subject

device has passed the IEC60601-1, IEC60601-1-2and ISO80601-2-61, so this difference does not raise different questions of safety and effectiveness.

Note2 SPO2 Accuracy & Pulse Rate Accuracy

The SPO2&Pulse rate Accuracy of subject device has slightly difference from the predicate device. But, the subject device's SPO2&Pulse rate Accuracy meets the requirement of ISO80601-2-61,so this difference also does not raise different questions of safety and effectiveness.

Note3 Material

The reusable spo2 sensor of both device have the same material of patient end, only the cable connecting with skin material is different, the subject device's is TPU, and the predicate device's is PVC. The patient end of Caremed disposable sensors is sponge adhesive, but the subject device meets the requirements of ISO10993-5/10, so this difference also does not raise different questions of safety and effectiveness.

According to contrast and analysis, the differences between subject device and predicate device does not raise different questions of safety and 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 test data

Clinical testing has been performed under an approved protocol with subject informed consent. Clinical hypoxia test results were obtained in human adult volunteers to validate the accuracy of Caremed Reusable & Disposable SPO2 Sensors versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

11. Conclusions

Based on the comparison, analysis, and the submitted performance data, Caremed Reusable & Disposable SPO2 Sensors are substantially equivalent to the predicate devices.