Shenzhen Coreray Technology, Ltd.
% Field Fu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
Room 1122, International Mayor Communication Center
No. 55 Shi Zhou Zhong Road
Nanshan, Shenzhen 518100
CHINA

Re: K173368
Trade/Device Name: Reusable SpO2 Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 24, 2018
Received: August 2, 2018

Dear Field Fu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173368

Device Name
Reusable SPO2 Sensor

Indications for Use *(Describe)*
Coreray Reusable SPO2 Sensor is intended to be used in hospital settings where patient care is offered by qualified healthcare personnel. The Reusable SPO2 Sensor is intended 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 05 510(k) Summary

5.1 Administrative Information

Date of Summary prepared	Aug. 24, 2017
Manufacturer information	Company title: Shenzhen Coreray Technology Co., Ltd Company address: ChuangYe Technology Park, 1th Dong Huan Road, Longhua New District, Shenzhen, 510000 P.R China. P.C.:518109 Contact person: Simon Fan Phone: +86-755-28839229 Fax: +86-755-28839229 E-mail: manager@core-ray.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: Room 1122, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen Contact person: Mr. Field Fu E-Mail: cefda13485@163.com

5.2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Reusable SpO_2 Sensor
Model:	CR001-3106A
Classification name:	Pulse Oximeter Sensor
Review Panel:	Cardiovascular
Product Code:	DQA
Device Class:	II

Regulation Number:	870.2700

5.3 Predicate Device Information

Sponsor:	Shenzhen Caremed Medical Technology Co., Ltd.
Device:	Caremed Reusable & Disposable SpO2 Sensors
510(K) Number:	K153184

Sponsor:	Solaris Medical Technology, Inc.
Device:	Solaris Reusable & Disposable SPO2 Sensors
510(K) Number:	K100077

5.4 Device Description

The Reusable SPO_2 Sensor is comprised of a connector and a cable which terminates into sensor housing.

The sensor contains two specific wavelength LEDs and a photo detector assembled into the sensor housing which separate by one housing half and the other half. The sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter.

One type of sensor housing is described in this submission:

Reusable finger clip sensor

The sensor has a labeling and specifications designed for compatibility with a specific monitor.

5.5 Intended Use/ Indications for Use

Coreray Reusable SPO_2 Sensor is intended to be used in hospital settings where patient care is offered by qualified healthcare personnel. The Reusable SPO_2 Sensor is intended for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) for adult patients weighing greater than 40kg.

5.6 Technological characteristics of the subject device compared to the predicate device

Predicate Device Information:

510(K) No.: K153184
Common name: Oximeter
Classification name: Oximeter
Production regulation: 21 CFR § 870.2700
Product code: DQA
Panel: Cardiovascular

510(K) No.: K100077
Common name: Pulse Oximeter Sensor
Classification name: Oximeter
Production regulation: 21 CFR § 870.2700
Product code: DQA
Panel: Cardiovascular

Comparison to predicate device:

Comparison item	Subject Device Reusable and disposable SPO2 sensor	Predicate Device K153184	Predicate Device K100077	Remarks
Product Code	DQA	DQA	DQA	same
Regulation Number	870.2700	870.2700	870.2700	same
Classification	II	II	II	
Intended use& Indications for Use	Coreray Reusable SPO_2 Sensor is intended to be	Caremed Reusable & Disposable SPO2 Sensors are	When used with a compatible patient monitor or a pulse	SE as K100077

	used in hospital settings where patient care is offered by qualified healthcare personnel. The Reusable SPO_2 Sensor is intended for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) for adult patients weighing greater than 40kg. Prescription device.	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.	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.	
Measurement Method	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	same
Light Emitting	Red: 660nm±10nm Infrared: 905nm±10nm	Red:660-666nm, Ired:880-950nm	Red:660-666nm, Ired:880-950nm	similar Within the range of the frequency of the predicate devices.
Signal Detection Method	Photodetector	Photodetector	Photodetector	same
SPO2 Accuracy	±3% (70-100%)	±3% (70-100%)	±2% (70-100%)	same as K153184, and complian ce with the ISO8060 1-2-61.
Pulse Rate Accuracy	±3(30-250bpm)	±3(30-250bpm)	±3(30-250bpm)	same
Applied population	Adult (≥40Kg)	Adult(≥40Kg) Pediatric(10-50Kg)	Adult(≥40Kg) Pediatric(10-50Kg) Neonatal (3-	SE as K100077

			10Kg)	
Measurement part	Fingers	Fingers or toes	Fingers or toes	SE
Sterile	No	No	No	same
Material	ABS, TPU, Silicone,	ABS, PVC, TPU, Silicone, sponge	ABS, PVC, Silicone and 3M	similar Passed the biocompatibility test.
Biocompatibility	Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization	same
Distal connector Design	clip	finger clip and sponge adhesive	soft tip and textile adhesive	clip design same as K153184
Electrical Performance and Safety	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	same

The subject device and the predicate device have the same intended use and similar technological characteristics; they both measure SpO2 values for the patients. Thus the subject device is substantially equivalent to the predicate devices.

5.7 Brief discussion of the nonclinical tests

Reusable SpO2 Sensor conforms to the following standards:
IEC 60601-1:2005+CORR.1:2006+CORR.2007+A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential

Performance.

IEC 60601-1-2: 2014 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

ISO 80601-2-61:2011 Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment

ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.

ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization.

5.8 Brief discussion of clinical tests

Clinical testing is conducted for validation of S_pO_2 the Coreray Reusable & Disposable SpO_2 Sensor.
The Reusable SpO_2 Sensor was satisfied the requirements of FDA guidance and ISO 80601-2-61:2011 in the range of 70%-100%SaO_2.

5.9 Other information (such as required by FDA guidance/Test)

Animal performance testing is not required and was not performed to demonstrate substantial equivalence of the Coreray Reusable SpO_2 Sensor.

5.10 Conclusions

Based on the above information, we conclude the subject device, Reusable SpO_2 Sensor, is substantially equivalent to the predicate device.