June 22, 2020

Shenzhen Coreray Technology., Ltd
Simon Fan
Manager
305, 307 Liangji Building, 1st Donghuan Road
Longhua New District
Shenzhen, 518109 Cn

Re: K192404
Trade/Device Name: Patient Monitoring Cable (SpO2 Extension Cable)
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA, DQA
Dated: May 15, 2020
Received: May 22, 2020

Dear Simon Fan:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K192404

Device Name
Patient Monitoring Cables (SpO2 Extension Cable)

Indications for Use *(Describe)*
Patient Monitoring Cables are intended to be used to connect sensors, placed at appropriate sites on the patient to a monitoring device for general monitoring by health care professional.

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

K192404

This is a traditional 510k submission, and there were no prior submissions for the subject device.

1. Submitter Information

Sponsor: Shenzhen Coreray Technology Co., Ltd.

Address: 305, 307 Liangji Building, 1st Donghuan Road Longhua New District, Shenzhen, Guangdong, China

Contact Person: Simon Fan

Title: General Manager

Phone: +86-755-28239229

E-mail: manager@core-ray.com

Summary prepared on 29 May, 2020

2. Subject Device Information

Type of 510(k) submission: Traditional

Trade/Device Name: Patient Monitoring Cables

Model: SpO2 Extension Cable CR002-5301

Classification Name: Cable, Transducer And Electrode, Patient, (Including Connector)

Review Panel: Cardiovascular

Classification Product Code: DSA, 21 CFR 870.2900

Regulation Class: 2

3. Predicate Device Information

Sponsor: Shenzhen Med-link Electronics Tech Co., Ltd.

Device Name: Cable/lead-wire (ECG, EKG, SpO2 and Invasive Blood Pressure)

Classification Name: Patient transducer and electrode cable (including connector)

510(k) number: K120010

Review Panel: Cardiovascular

Product Code: DSA

Regulation Number: 21 CFR 870.2900

4. Reference Device information

Sponsor: Curbell Medical Products, Inc.

Device Name: Curbell Patient Monitoring Cables

Classification Name: Patient transducer and electrode cable (including connector)

510(k) number: K182220

Review Panel: Cardiovascular

Product Code: DSA

Regulation Number: 21 CFR 870.2900

5. Device Description

Patient Monitoring Cables (SpO2 Extension Cable, CR002-5301) is comprised of Plug, Cable/Leadwires and Connector. It's intended to plug into monitoring device and connect with SpO2 sensor, for transmitting signals which generated by SpO2 sensor to monitoring device.

By using the same types of construction and technological characteristics to the compatible patient monitor and SpO2 sensor, Patient Monitoring Cables (SpO2 Extension Cable, CR002-5301) can avoid measured date corrupted.

The compatible patient monitor is Nellcor N-595 Pulse Oximeter and compatible SpO2 sensor is Nellcor OxiMax Durasensor adult oxygen sensor DS-100A, which both are cleared under K012891.

6. Intended Use

Patient Monitoring Cables are intended to be used to connect sensors, placed at appropriate sites on the patient to a monitoring device for general monitoring by health care professional.

7. Standard Utilization

Standards No.	Title of Standard	Edition	FDA Recognition No.	Date of Recognition
ANSI AAMI ES 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety	2005/(R)2012 And A1:2012,	19-4	07/09/2014
ISO 80601-2-61	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	2017-12	1-139	09/17/2018
ANSI AAMI EC53	ECG trunk cables and patient leadwires	2013	3-129	07/09/2014

8. Test Summary

Patient Monitoring Cables has been evaluated the safety and performance by lab bench testing according to the following standards:

- ✉ IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance, 2005+A1:2012

  Note: *Although IEC 60601-1 2005+A1: 2012 is no longer a FDA-recognized standard, the subject device has assessed the differences to US national standard (ANSI AAMI 60601-1: 2005/(R)2012 And A1:2012), and the test report attaches the compliance.*

- ✉ ANSI AAMI EC53: 2013 ECG Trunk Cables And Patient Leadwires
- ✉ ISO 80601-2-61 Medical electrical equipment - Part 2-61: Requirements for basic

safety and essential performance of pulse oximeter equipment

Patient Monitoring Cables has also been evaluated the performance accuracy through integrity testing, which proves that no measured data corrupt during communication between SpO2 sensors and host monitors.

9. Biocompatibility

There is one kind of patient-directly contacting component in the subject device as the following list.

Component of Device Requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Cable Jacket	TPU	Surface-contacting device: Patient Skin	< 24 hours

We conduct biocompatibility test on the SpO2 extension cable CR002-5301 including the following:

- Cytotoxicity
- Sensitization
- Irritation

10. Comparison to Predicate/Reference Device

Compare with predicate/reference devices, the subject device is very similar in design principle, intended use, material and the applicable standards. The differences between subject device and predicate/reference devices do not raise any new questions of safety or effectiveness.

Elements of comparison	Subject Device	Predicate Device	Reference device	Verdict
Manufacturer	Shenzhen Coreray Technology Co., Ltd.	Shenzhen Med-link Electronics Tech Co., Ltd.	Curbell Medical Products, Inc.	--
510K number	K192404	K120010	K182220	--

Elements of comparison	Subject Device	Predicate Device	Reference device	Verdict
Product Name	Patient Monitoring Cables SpO2 Extension Cable CR002-5301	Cable/lead-wire (ECG, EKG, SpO2 and Invasive Blood Pressure)	Curbell Patient Monitoring Cables	--
Classification Name	Patient transducer and electrode cable (including connector)	Patient transducer and electrode cable (including connector)	Patient transducer and electrode cable (including connector)	SE
Regulation Class	2	2	2	SE
Regulation Number	21 CFR 870.2900	21 CFR 870.2900	21 CFR 870.2900	SE
Product Code	DSA	DSA	DSA	SE
OTC & Rx	Rx	Rx	Rx	SE
Indications for Use	Patient Monitoring Cables are intended to be used to connect sensors, placed at appropriate sites on the patient to a monitoring device for general monitoring by health care professional.	Shenzhen Med-link Cable / lead-wire are intended to be used with ECG, EKG, SpO2 and Invasive Blood Pressure monitoring devices. The Cable / lead-wire are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by heath care professional.	Curbell patient cables are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.	SE Note 1
Design	Plug, Cable/Leadwires and connectors	Connectors on each cable end and a shielded bulk cable	Patient trunk cable, Patient leadwire and Electrode/sensor connectors	SE Note 1
Usage	Reusable	Reusable	Reusable	SE
Cable lengths	8ft	Various specified standard lengths	Patient trunk cable: 7-20ft Patient leadwire: 18''-120''	SE Note 2
Wire material	Shielded & Unshielded Copper with TPU jacket	Shielded & Unshielded Copper with PVC or TPU jacket	Shielded & Unshielded Copper with PVC or TPU jacket	SE Note 2
Sterility	Non-sterile	Non-sterile	Non-sterile	SE
Biocompatibility	Meets ISO 10993-5	Meets ISO 10993-5 Cytotoxicity, ISO	Meets ISO 10993-5	SE

Elements of comparison	Subject Device	Predicate Device	Reference device	Verdict
	Cytotoxicity, ISO 10993-10 Sensitization and Irritation	10993-10 Sensitization and Irritation	Cytotoxicity, ISO 10993-10 Sensitization and Irritation	
Electrical safety and Performance	IEC 60601-1 AAMI/ANSI EC53 ISO 80601-2-61	IEC 60601-1 AAMI/ANSI EC53	IEC 60601-1 AAMI/ANSI EC53	SE

Note 1

The subject device is only intended to connect the SpO2 sensor to a monitoring device, while the predicate device could be applied to ECG, EKG, SpO2, IBP monitoring. So, the difference does not affect the safety and effectiveness.

Note 2

Although the design and description between the predicate device and subject device have few differences, there is only one model of subject device complied with IEC 60601-1 and AAMI/ANSI EC53, and the cable length and material of subject device also applied to the predicate device, so the differences do not affect the safety and effectiveness.

11. Summary for clinical test

Clinical performance is not deemed necessary.

12. Conclusion

The subject device Patient Monitoring Cables has all features of the predicate/reference devices and has the same intended use as the predicate. The difference in technological features does not raise different questions of safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate device.