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
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.


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 D. 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
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)*
- [x] 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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASstaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
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**

<table>
<thead>
<tr>
<th>Standards No.</th>
<th>Title of Standard</th>
<th>Edition</th>
<th>FDA Recognition No.</th>
<th>Date of Recognition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 80601-2-61</td>
<td>Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment</td>
<td>2017-12</td>
<td>1-139</td>
<td>09/17/2018</td>
</tr>
<tr>
<td>ANSI AAMI EC53</td>
<td>ECG trunk cables and patient leadwires</td>
<td>2013</td>
<td>3-129</td>
<td>07/09/2014</td>
</tr>
</tbody>
</table>

8. **Test Summary**

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


  **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.

<table>
<thead>
<tr>
<th>Component of Device Requiring Biocompatibility</th>
<th>Material of Component</th>
<th>Body Contact Category (ISO 10993-1)</th>
<th>Contact Duration (ISO 10993-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cable Jacket</td>
<td>TPU</td>
<td>Surface-contacting device: Patient Skin</td>
<td>&lt; 24 hours</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Elements of comparison</th>
<th>Subject Device</th>
<th>Predicate Device</th>
<th>Reference device</th>
<th>Verdict</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Shenzhen Coreray Technology Co., Ltd.</td>
<td>Shenzhen Med-link Electronics Tech Co., Ltd.</td>
<td>Curbell Medical Products, Inc.</td>
<td>--</td>
</tr>
<tr>
<td>510K number</td>
<td>K192404</td>
<td>K120010</td>
<td>K182220</td>
<td>--</td>
</tr>
<tr>
<td>Elements of comparison</td>
<td>Subject Device</td>
<td>Predicate Device</td>
<td>Reference device</td>
<td>Verdict</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------</td>
<td>-----------------</td>
<td>------------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Product Name</strong></td>
<td>Patient Monitoring Cables</td>
<td>Cable/lead-wire (ECG, EKG, SpO2 and Invasive Blood Pressure)</td>
<td>Curbell Patient Monitoring Cables</td>
<td>--</td>
</tr>
<tr>
<td><strong>Classification Name</strong></td>
<td>Patient transducer and electrode cable (including connector)</td>
<td>Patient transducer and electrode cable (including connector)</td>
<td>Patient transducer and electrode cable (including connector)</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Regulation Class</strong></td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Product Code</strong></td>
<td>DSA</td>
<td>DSA</td>
<td>DSA</td>
<td>SE</td>
</tr>
<tr>
<td><strong>OTC &amp; Rx</strong></td>
<td>Rx</td>
<td>Rx</td>
<td>Rx</td>
<td>SE</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>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.</td>
<td>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 health care professional.</td>
<td>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.</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Plug, Cable/Leadwires and connectors</td>
<td>Connectors on each cable end and a shielded bulk cable</td>
<td>Patient trunk cable, Patient leadwire and Electrode/sensor connectors</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Usage</strong></td>
<td>Reusable</td>
<td>Reusable</td>
<td>Reusable</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Cable lengths</strong></td>
<td>8ft</td>
<td>Various specified standard lengths</td>
<td>Patient trunk cable: 7-20ft Patient leadwire: 18”-120”</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Wire material</strong></td>
<td>Shielded &amp; Unshielded Copper with TPU jacket</td>
<td>Shielded &amp; Unshielded Copper with PVC or TPU jacket</td>
<td>Shielded &amp; Unshielded Copper with PVC or TPU jacket</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Sterility</strong></td>
<td>Non-sterile</td>
<td>Non-sterile</td>
<td>Non-sterile</td>
<td>SE</td>
</tr>
<tr>
<td><strong>Biocompatibility</strong></td>
<td>Meets ISO 10993-5</td>
<td>Meets ISO 10993-5 Cytotoxicity, ISO</td>
<td>Meets ISO 10993-5</td>
<td>SE</td>
</tr>
</tbody>
</table>
### Elements of comparison

<table>
<thead>
<tr>
<th>Subject Device</th>
<th>Predicate Device</th>
<th>Reference device</th>
<th>Verdict</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxicity, ISO 10993-10 Sensitization and Irritation</td>
<td>10993-10 Sensitization and Irritation</td>
<td>Cytotoxicity, ISO 10993-10 Sensitization and Irritation</td>
<td>SE</td>
</tr>
</tbody>
</table>

**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.