April 2, 2023

Beijing Rongrui-Century Science & Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K222370
Trade/Device Name: 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
Dated: March 3, 2023
Received: March 3, 2023

Dear Ray Wang:

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,

James J. Lee -S

James J. Lee, Ph.D.
Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222370

Device Name
SpO2 Extension Cable

Indications for Use *(Describe)*
SpO2 Extension Cables are intended to be used to connect SpO2 sensors, placed at appropriate sites on the patient to a monitoring device for SpO2 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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The assigned 510(k) Number: K222370

Tab #3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation:2023/03/29

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: SpO2 Extension Cable
Common Name: Cable, Transducer And Electrode, Patient, (Including Connector)

Regulatory Information
Classification Name: Cable, Transducer And Electrode, Patient, (Including Connector)
Classification: II
Product Code: DSA
Regulation Number: 21 CFR 870.2900
Review Panel: Cardiovascular

Indication for use Statement:

SpO2 Extension Cables are intended to be used to connect SpO2 sensors, placed at appropriate sites on the patient to a monitoring device for SpO2 monitoring by health care professional.

Device Description:

SpO2 Extension Cables are intended to be used to connect SpO2 sensors, placed at appropriate sites on the patient to a monitoring device for SpO2 monitoring by health care professional.
The SpO2 Extension Cable is the replacements for similar cables manufactured by Original Equipment Manufacturers (OEM) and other third party after market manufacturers for their respective monitors.
The SpO2 Extension Cable 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, the SpO2 Extension Cable can avoid measured data corrupted.
The compatible sensors and monitors are shown in the following table:

NO.	Model	Compatible Rongrui Sensor	Compatible Monitors & Nellcor OEM Boards
1	RCT006	RSJ002A, RSA002DN RSJ002I, RSA002DI RST002A, RSA002DP RST002I, RSA002DA RSW002N, RSY002N	NELLCOR: N-600X、N-595
2	RCT018	RSJ001A,RSJ001I, RST001A,RST001I, RSW001N,RSY001N, RSA001DN,RSA001DI, RSA001DP,RSA001DA	Philips: CM100、MP2、X2、MP5

5. Identification of Predicate Device(s)

Predicate Device
K192404
Patient Monitoring Cables (SpO2 Extension Cable)
Shenzhen Coreray Technology Co., Ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- 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.
- IEC 60601-1:2012, 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 Compatibility-Requirements And Tests
- ISO 80601-2-61:2017 Medical electrical equipment-Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ANSI AAMI EC53:2013/(R)2020 ECG trunk cables and patient leadwires

SpO2 Extension Cable has also been evaluated the performance accuracy through Compatibility testing, which proves that no measured data corrupt during communication between SpO2 sensors and host monitors.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device	Predicate Device	Remark
Product name	SpO2 Extension Cable	Patient Monitoring Cables (SpO2 Extension Cable) K192404	/
Classification	21 CFR 870.2900	21 CFR 870.2900	SAME

Regulation			
Classification	II	II	SAME
Product Code	DSA	DSA	SAME
Common Name	Cable, Transducer And Electrode, Patient, (Including Connector)	Cable, Transducer And Electrode, Patient, (Including Connector)	SAME
Indications for use	SpO2 Extension Cables are intended to be used to connect SpO2 sensors, placed at appropriate sites on the patient to a monitoring device for SpO2 monitoring by health care professional.	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.	SAME
Design	Plug, Cable/Leadwires and connectors	Plug, Cable/Leadwires and connectors	SAME
Usage	Reusable	Reusable	SAME
Cable lengths	2m±10%	8ft	Difference1
Wire material	Shielded & Unshielded Copper with PVC or TPE jacket	Shielded & Unshielded Copper with TPU jacket	Difference2
Sterility	Non-sterile	Non-sterile	SAME
Biocompatibility	Meets ISO 10993-5 Cytotoxicity, ISO 10993-10 Sensitization and Irritation	Meets ISO 10993-5 Cytotoxicity, ISO 10993-10 Sensitization and Irritation	SAME
Electrical safety and Performance	IEC 60601-1 ISO 80601-2-61 ANSI AAMI EC53	IEC 60601-1 ISO 80601-2-61 ANSI AAMI EC53	SAME
EMC	IEC 60601-1-2	IEC 60601-1-2	SAME

Analysis：

Difference 1：

There is difference on the cable length, the cable length of the proposed device is 2m±10% (Approximately 6.6 ft), the cable length of the predicate device is 8ft, but these cables are same function , the cable length difference would not affect its safety and effectiveness.

Difference 2：

Although the wire material between the proposed device and predicate device have few differences, the proposed device comply with electrical safety standard IEC 60601-1 and the performance standard ISO 80601-2-61 and ANSI AAMI EC53, so the differences would not affect its safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.