May 2, 2025

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

Re: K242986
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, DQA
Dated: September 25, 2024
Received: September 26, 2024

Dear Wang Ray:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

for Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242986

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: _____K242986_____

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:2025/03/31

2. Sponsor Identification

Beijing Rongrui-Century Science & Technology Co., Ltd.
3rd Floor, West zone, No.1 Building, No.7 Yard, Fengxian middle Road, HaiDian District, Beijing, 100094, P.R.China.

Contact Person: Zhenghua Zhang
Position: Quality Manager
Tel: +86-13371720965
Fax: +86-10-58711218
Email: zl05@r-rui.onaliyun.com

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, 102401, China

Tel: +86-18910677558
Fax: +86-10-56335780
Email: information@believe-med.com

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, DQA
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 Cable consists of two parts: the SpO2 patient cable and the adapter. The SpO2 patient cable is used for connecting the monitors, and the adapter is used for connecting the SpO2 patient cable and the SpO2 sensor.

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.
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 proposed device was modification from the legally marketed (existing) device “SpO2 Extension Cable”/K222370, manufactured by “Beijing Rongrui-Century Science & Technology Co., Ltd.”, same as the sponsor of this submission.

Compared to the initial product (K222370), only the structure of the SpO2 Extension Cable has changed. Originally a non-separable complete extension cable, now an extension cable can be separated into two parts, called the SpO2 patient cable and the adapter.

The type of instrument connector (which connects one end of the monitoring device) for the SpO2 patient cable is 20pin, there are four types pairing interfaces between SpO2 patient cable and adapter, the pairing interfaces name for the SpO2 patient cable and adapter connection is DB9F-LNCS, MLNCS-MLNCS, LNOP-LNOP, RD-RD and the other end of the adapter connecting to SpO2 sensor is DB9F. Adapters are divided into two categories: with cable and without cable. Adapters for each type of interface are available with and without cables.

The materials and the manufacturing process technology are the same.

We selected K222370 as our reference device. Detailed comparison information can be found in the 510k Summary.

The compatible sensors and monitors are shown in the following table:

SpO2 patient cable Model	Adapter Model	Compatible Rongrui Sensor	Compatible Monitors Manufacture Masimo Corporation
RCT032	RCT083-AL	RSJ002A, RSA002DN, RSJ002I, RSA002DI, RST002A,RSA002DP, RST002I, RSA002DA, RSW002N, RSY002N	Masimo Radical-7 (K212161)
	RCT083-CL		
RCT032-M	RCT083-AM		
	RCT083-CM		
RCT032-P	RCT083-AP		
	RCT083-CP		
RCT032-R	RCT083-AR		
	RCT083-CR		

5. Identification of Predicate Device(s)

Predicate Device
K222370
SpO2 Extension Cable
Beijing Rongrui-Century Science & 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 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, 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	SpO2 Extension Cable K222370	/
Classification Regulation	21 CFR 870.2900	21 CFR 870.2900	SAME
Classification	II	II	SAME
Product Code	DSA, DQA	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.	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.	SAME
Structure	Separate extension cable	Non-separable extension cable	Different
Usage	Reusable	Reusable	SAME
Cable lengths	2m±10%	2m±10%	SAME
Wire material	Shielded & Unshielded Copper with PVC or TPE jacket	Shielded & Unshielded Copper with PVC or TPE jacket	SAME
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

Different--Structure:

The structure of the proposed device and predicate device is minor different. The predicate device is a non-separable complete extension cable, the proposed device can be separated into two parts:SpO2 patient cable and the adapter. Though their structure is different, they all contain Plug, Cable/Leadwires and connectors. And the proposed device comply with electrical safety standard IEC 60601-1,IEC6061-1-2, the performance standard ISO 80601-2-61 and ANSI AAMI EC53. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

9. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, SpO2 Extension Cable, cleared under K222370.