August 16, 2024

Shenzhen Mecun Medical Supply Co., Ltd.
Zheng Bo
General Manager
2nd Level, 2nd Building, Fuqiang S&T Park, 6 Ailian
Industrial Park, Zhugushi, Wulian Community
Shenzhen, Guangdong province 518000
China

Re: K231979
Trade/Device Name: Mecun SpO2 sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: April 8, 2024
Received: April 8, 2024

Dear Zheng Bo:

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.

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231979

Device Name
Mecun SpO2 sensor

Indications for Use *(Describe)*
Mecun SpO2 sensor is indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40kg. The sensor is intended to be used in hospital settings where patient care is offered by qualified healthcare personnel.

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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510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1. Submitter

Submitter's Name	Shenzhen Mecun Medical Supply Co., Ltd.
Contact Person	Zheng Bo
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E-mail	james@szcsqy.com; manager@mecun.com
Data preparation	April 8th, 2024

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Mecun SpO2 sensor
Classification name:	Oximeter
Classification:	II
Review Panel:	Cardiovascular devices
Product Code:	DQA
Regulation Number:	870.2700

3. Predicate Device Information

Trade Name	Reusable and Disposable SpO2 Sensors
510(k) Number	K201360
Classification name	Oximeter
Classification:	II
Review Panel:	Cardiovascular devices
Product code	DQA
Regulation No.	870.2700

4. Device Descriptions

Mecun SpO2 Sensor consists of a connector, cable and patient sensor terminal. The optical components of sensor contain a LED emitter and a LED detector assembled into the non-woven

housing. The sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter.
The sensor shall be connected to its corresponding monitor (Nellcor, N-600x cleared in K060576), which are intended for continuous monitoring of functional arterial oxygen saturation and pulse rate in non-invasive way with legally marketed devices.

5. Intended Use/Indications for Use

Mecun SpO2 sensor is indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40kg. The sensor is intended to be used in hospital settings where patient care is offered by qualified healthcare personnel.

6. Comparisons of technological characteristics with the predicate device

Mecun SpO2 sensor and Xinkang SpO2 sensors (K201360) are similar in intended use, compositions, functions, scientific technology, materials and method of operation, the following table provides a comparison summary:

Comparison item	Subject Device	Predicate Device (K201360)	Remark
Manufacturer	Shenzhen Mecun Medical Supply Co., Ltd.	Xinkang Medical Instrument Co., Ltd.	/
Product name	Mecun SpO2 sensor	Reusable and Disposable SpO2 Sensors	/
Model	Adult/disposable: MC-FN011M	Adult/disposable: XDAN Adult/reusable: XSAE3	Same (only disposable type included)
Product Code	DQA	DQA	Same
Regulation Number	870.2700	870.2700	Same
Classification	II	II	Same
Intended use& Indications for Use	Mecun SpO2 sensor is indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40kg. The sensor is intended to be used in hospital settings where patient care is offered by qualified healthcare personnel.	The Reusable & Disposable SPO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult patients weighing greater than 40kg. The sensors are intended to be used in hospital settings where patient care is offered by qualified healthcare personnel.	Same
Measurement Method	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption	Same
Light Emitting	Red: 660nm Infrared: 940nm	Red: 660nm±3nm Infrared: 880-950nm	Similar
Signal Detection	Photodetector	Photodetector	Same

Method			
SpO2 Accuracy	±3% (70-80%) ±2% (80-100%) Undefined (< 70%)	±3% (70-100%) Undefined (< 70%)	Note 1
Pulse Rate Accuracy	±3(20-250bpm)	±3(30-250bpm)	Similar
Applied population	Adult (≥40Kg)	Adult (≥40Kg)	Same
Cable length	MC-FN011M: 900±50mm	XDAN: 1m	Similar
Measurement part	Finger	Finger	Same
Sensor terminal	Non-woven	Non-woven	Same
Sterility status	Non-sterile	Non-sterile	Same
Compatible monitor	Nellcor	Nellcor	Same
Sterile	No	No	Same
Material contacted with patient	Sensor housing: non-woven Cable: PVC	Sensor housing: non-woven Cable: PVC	Same
Biocompatibility	Cytotoxicity Skin irritation Skin sensitization	Cytotoxicity Skin irritation Skin sensitization	Same
Electrical Performance and Safety	IEC60601-1, IEC60601-1-2, ISO80601-2-61	IEC60601-1, IEC60601-1-2, ISO80601-2-61	Same

Note 1:
The SpO2 Accuracy of subject device has slightly difference from the predicate device. But the subject device's SpO2 Accuracy meets the requirement of ISO80601-2-61 as well as the requirements of FDA guidance of pulse oximeters, so this difference also does not raise any safety and effectiveness issue.

7. Performance data

The subject device conforms to the following standards:

7.1 Biocompatibility testing

The biocompatibility evaluation for Mecun SpO_2 Sensor was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The terminal sensor and cable are considered to be contacted with patient's intact skin for duration of less than 24 hours. The biocompatibility testing includes the following:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

7.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, and the results show that the subject device complies with the following standards:

- IEC 60601-1: 2005 + A1:2012 + A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 + A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests standard for EMC
- ISO 80601-2-61: 2017 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of Pulse Oximeter Equipment standard for performance effectiveness

7.3 Clinical study

Clinical studies were conducted to verify the accuracy of subject device. The clinical studies were conducted per following standards:

- ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment
- Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff Clinical testing has been performed under an approved protocol with subject informed consent

7.4 Summary

Based on the non-clinical performance and clinical data as documented in the device development, the subject device has a safety and effectiveness profile that is similar to the predicate device.

8. Conclusions

Based on device comparison information and performance data, the subject device is as safety and effectiveness as predicate device, and the differences in technological characteristics do not raise any new issue of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.