



August 13, 2025

Unimed Medical Supplies, Inc.
Huanyu Zeng
Regulatory affairs specialist
Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, Baoan
District
Shenzhen,
China

Re: K250931

Trade/Device Name: Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U403-117); Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U103-117); Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U410-121); Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U110-121);

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: Class II

Product Code: DQA

Dated: July 17, 2025

Received: July 17, 2025

Dear Huanyu Zeng:

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](https://www.fda.gov/training-and-continuing-education/cdrh-learn)) 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 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K250931

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Please provide the device trade name(s).

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Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U403-117);
Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U103-117);
Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U410-121);
Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U110-121)

Please provide your Indications for Use below.

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Unimed Reusable 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 30 kg and pediatric patients weighing 10-50 kg. These devices are for prescription use only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510K Summary

1. Submitter

Date Prepared: March 28, 2025
Submitter/Manufacturer: Unimed Medical Supplies Inc.
 Bld#8, Nangang 3rd Industrial Park, Tangtou,
 Shiyang, Baoan District, Shenzhen, China 518108
 FDA Establishment Number: 3007307487
Contact: Zeng Huanyu
 RA Specialist
 Tel: +86-755 26695165
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510(k) Submission Type This is a Traditional 510(k).

2. Proposed Device

Trade Name: Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U403-117)
 Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U103-117)
 Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U410-121)
 Unimed Reusable SpO2 Sensors (-117 and -121 Series) (U110-121)
Common Name: Oximeter Sensor
Model Numbers U403-117, U103-117, U410-121, U110-121
Classification: Medical Specialty: Cardiovascular
 Regulation: 21 CFR 870.2700 – Oximeter
 Product Code: DQA
 Class: II

3. Predicate Device

Predicate Device	
510(K) No.	Trade Name
K093881	TRUSIGNAL SPO2 FINGER SENSOR, TRUSIGNAL SPO2 EAR SENSOR, TRUSIGNAL SPO2 WRAP SENSOR

Reference Device	
510(K) No.	Trade Name
K151063	Monitor B40

4. Device description

The subject devices are Unimed Reusable SpO₂ Sensors intended for non-invasive measurement of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (PR) in clinical settings. The sensors are designed for compatibility with GE B40i, and are supplied non-sterile.

Each sensor consists of a connector, a cable, and a reusable patient-contacting sensor element incorporating a light-emitting diode (LED) and photodetector (PD). The sensors are available in multiple configurations, including finger clip, wrap, and soft-tip types, to accommodate various patient needs and anatomical sites.

The subject devices operate on the same principle and share similar design features, materials, and performance characteristics as the predicate device.

5. Intended use/Indications for use

Unimed Reusable 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 30 kg and pediatric patients weighing 10-50 kg. These devices are for prescription use only.

6. Comparison to predicate devices

Feature	Subject Device (Model: U403-117, U103-117, U410-121, U110-121)	Predicate Device (K093881)	Comparison to Predicate/Reference Devices
General Information			
Device name	Unimed Reusable SpO ₂ Sensors	TruSignal® SpO ₂ Sensors and Interconnect Cables	/
Classification Regulation/ Product Code	21 CFR 870.2700, Class II/DQA	21 CFR 870.2700, Class II/DQA	Identical
Intended use/Indications for use	Unimed Reusable SpO ₂ Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO ₂) and pulse rate (PR) for adult patients weighing greater than 30 kg and pediatric patients weighing 10-50 kg. These devices are for prescription use only.	<u>TS-F-D</u> The Finger Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO ₂) and pulse rate monitoring. Patient weight range > 20 kg (> 44 pounds) <u>TS-E-D</u> The Ear Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO ₂) and pulse rate monitoring. The headband is single-patient use. Patient weight range > 10 kg (> 22 pounds)	Substantially equivalent

Feature	Subject Device (Model: U403-117, U103-117, U410-121, U110-121)	Predicate Device (K093881)	Comparison to Predicate/Reference Devices
		<u>TS-W-D</u> The Wrap Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO₂) and pulse rate monitoring. The tape and foam wrap are single-patient use. Patient weight range > 3 kg (> 66 pounds) <u>TS-SE-3</u> The Sensitive Skin Sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO₂) and pulse rate monitoring. The tape and foam wrap are single-patient use. Patient weight range All patients <u>TS-AF-10 and TS-AF-25</u> The AllFit Sensor is a single-patient use adhesive sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO₂) and pulse rate monitoring. Patient weight range	

Feature	Subject Device (Model: U403-117, U103-117, U410-121, U110-121)	Predicate Device (K093881)	Comparison to Predicate/Reference Devices
		All patients <u>Trusignal SpO₂ Interconnect cables</u> The Interconnect Cable is a reusable cable intended for use for all patients for continuous non-invasive arterial oxygen saturation (SpO₂) and pulse rate monitoring when used with a compatible SpO₂ sensor.	
Principle of operation	Two-wavelength relative optical absorption	Two-wavelength relative optical absorption	Same
Key performance specifications/ characteristics			
Intended patient population	Adult/Pediatric	TS-F-D: Patient weight range > 20 kg	Substantially equivalent
		TS-E-D: Patient weight range > 10 kg	
		TS-W-D: Patient weight range > 3 kg	
Intended application site	Finger	TS-F-D: Finger, toe	Substantially equivalent
		TS-E-D: Ear	
		TS-W-D: Finger, toe, palm of the hand, side of the foot	
Prescription or OTC	Rx Only	Rx Only	Identical
Use type	Reusable	Reusable	Identical
Sensor Structure Composition	Sensor connector, cable, LED	Sensor connector, cable, LED&PD,	Substantially equivalent ¹

Feature	Subject Device (Model: U403-117, U103-117, U410-121, U110-121)	Predicate Device (K093881)	Comparison to Predicate/Reference Devices
	(660nm/880nm/940nm) &PD, finger clip	finger clip/ear clip/wrap	
Performance (Arms)			
Saturation Accuracy, No Motion (70-100%)	±3%	±2%	Substantially equivalent ²
Pulse Rate Accuracy, No Motion			
	±2 bpm (30-250 bpm)	±2 bpm (30 to 250 bpm)	Substantially equivalent ³
Environmental			
Operating Temperature	5 to 40 °C	-40° to 60°C	Substantially equivalent
Operational/Storage Humidity	10 to 85%	5 to 95%	Substantially equivalent
Biocompatibility	Pass ISO 10993 cytotoxicity, skin irritation and skin sensitivity tests	Pass ISO 10993 cytotoxicity, skin irritation and skin sensitivity tests	Identical
Energy source	Monitor power supply	Monitor power supply	Identical

Note:

1. Subject devices have passed biocompatibility testing, with qualified bench testing and clinical testing results. Therefore, sensor structure composition is considered substantially equivalent.
2. Both Subject Device and Predicate Device have met the SpO₂ accuracy per Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff and are therefore considered substantially equivalent.
3. According to the requirements of "201.12.1.104 Pulse rate ACCURACY" of ISO 80601-2-61:2017, both Subject Device and Predicate Device have validated accuracy over the claimed pulse range and are therefore considered substantially equivalent.

7. Verification and validation testing

Non-clinical test data

Non-clinical tests were conducted to verify that the proposed devices met all design specifications as was Substantially Equivalent (SE) to the predicate devices. The conducted non-clinical tests conformed to the following the recognized standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020)
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014+AMD1:2020)
- ISO 80601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2017, COR1: 2018)
- ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation

The subject sensors include finger clip housing and silicone pad as patient-contacting components. The type of contact is contact with intact skin and the contact duration is defined as prolonged exposure per ISO 10993-1:2018 (medical devices whose cumulative sum of single, multiple or repeated contact time is likely to exceed 24 h but not exceed 30 d). Therefore, our biocompatibility testing has been specifically designed to meet the corresponding endpoint assessment requirements, including the following tests:

- Cytotoxicity
- Skin sensitization
- Skin irritation

The results of these tests demonstrate the biocompatibility of the subject devices.

Clinical test data

A clinical study was conducted under an approved protocol with subject informed consent to determine the accuracy of proposed device. The clinical studies were conducted per following standards:

- ISO 80601-2-61 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 hypoxia test results were obtained in human adult volunteers (the study population includes sufficient darkly pigmented subjects) to validate the accuracy of the subject devices versus arterial oxygen saturation (SaO₂) as determined by co-oximetry.

Twelve subjects were enrolled for the clinical study. The Fitzpatrick Scale was used to determine their skin pigmentation scores. Three dark subjects (Fitzpatrick Type 5-6) in this study allow a proper evaluation of the sensor accuracy in dark population. The study contains more than the minimum 200 data points, and the clinical study results support device accuracy claims for the specified saturation range.

8. Substantial Equivalence Statement

Based on the comparison, analysis, and the submitted verification and validation data, Unimed believes that the Unimed Reusable SpO₂ Sensors are as safe and effective and are substantially equivalent to the predicate device.