



February 6, 2025

Unimed Medical Supplies, Inc.
Huanyu Zeng
Regulatory Affairs Specialist
Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan
Baoan District
Shenzhen, 518108
China

Re: K242580

Trade/Device Name: Unimed Reusable Finger Clip SpO2 Sensors (U103-125); Unimed Reusable
Finger Clip SpO2 Sensors (U403-254); Unimed Reusable Finger Clip SpO2
Sensors (U103-254); Unimed Reusable Finger Clip SpO2 Sensors (U403-125)

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: Class II

Product Code: DQA

Dated: December 31, 2024

Received: December 31, 2024

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>) 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

Submission Number (if known)

K242580

Device Name

Unimed Reusable Finger Clip SpO2 Sensors (U103-125);
Unimed Reusable Finger Clip SpO2 Sensors (U403-254);
Unimed Reusable Finger Clip SpO2 Sensors (U103-254);
Unimed Reusable Finger Clip SpO2 Sensors (U403-125)

Indications for Use (Describe)

Unimed Reusable Finger Clip 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.

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.

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."

510(K) Summary

1. Submitter

Date Prepared: Dec. 27, 2024
Submitter/Manufacturer: Unimed Medical Supplies Inc.
Bld#8, Nangang 3rd Industrial Park, Tangtou,
Shiyan, Baoan District, Shenzhen, China 518108
FDA Establishment Number: 3007307487
Contact: Zeng Huanyu
RA Specialist
Tel: +86-755 26695165
E-mail: zenghy@unimed.cn
510(k) Submission Type This is a Traditional 510(k).

2. Proposed Device

Trade Name: Unimed Reusable Finger Clip SpO₂ Sensors
Common Name: Oximeter Sensor
Classification: Medical Specialty: Cardiovascular
Regulation: 21 CFR 870.2700 – Oximeter
Product Code: DQA
Class: II

3. Predicate Device

510(K) No.	Trade Name
K142832	Unimed Disposable And Reusable Spo2 Sensors

4. Device description

The subject devices, Unimed Reusable Finger Clip SpO₂ Sensors, are fully compatible reusable sensors for use with monitors that incorporate Masimo technology. These sensors are supplied non-sterile.

The subject sensors consist of a plug/connector (U403-125 and U103-125 with M8 sensor connector, and U403-254 and U103-254 with M10 sensor connector), a cable, and a patient-contacting (finger clip) where light-emitting diode (LED) and photodetector (PD) are located. The subject sensors share the same principle of operation as the predicate device for functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (PR) measurements. Also, the subject sensors have identical material composition and

performance characteristics to the predicate device.

The compatibility of the sensors is validated with specific monitor, as shown below:

Subject device	Compatible monitor
U403-254	Masimo Radical-7
U103-254	
U403-125	
U403-125	

Compared with the predicate device (U403-125) in K142832, the subject devices have the following changes:

- Change in photodetector (light receiving part of the sensor) with the same spectral wavelength and shorter response time;
- Change in size or interface connector. Specifically, U103-125 is designed in smaller finger clip size for pediatric use, and U403-254 and U103-254 (smaller finger clip size as U103-125) are designed with a change in the interface connector for expanded compatible options with the same monitor.

Also, the labeling has been revised to increase clarity and accommodate our product launch strategy without affecting safety and effectiveness of the product. Refer to the Summary of Labeling Change for details.

The purpose of the submission is to receive clearance to market U103-125, U403-254, and U103-254 under their own 510k and approval for changes to the cleared device U403-125.

5. Intended use/Indications for use

Unimed Reusable Finger Clip 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 device

The subject devices, U403-125, U103-125, U403-254, U103-254, and the predicate device, Unimed Disposable and Reusable SpO₂ Sensors (K142832) are compared in the following substantial equivalence table.

Feature	Subject Device (Model: U403-254, U103-254, U103-125, U403-125)	Predicate Device (K142832)	Comparison to Predicate Device
General Information			
Device name	Unimed Reusable Finger Clip SpO ₂ Sensors	Unimed Disposable and Reusable SPO2 Sensors	/
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 Finger Clip 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.	Unimed Disposable and Reusable SPO2 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 40 kg, pediatric patients weighing 10 -50 kg, and neonatal patients weighing no less than 3 Kg.	Equivalent. The intended population is reduced based on the models in the submission, and the statement of “for prescription use only” is added in the indications for use to better prevent negligence.
Principle of operation	Two-wavelength relative optical absorption	Two-wavelength relative optical absorption	Same
Key performance specifications/ characteristics			
Intended patient population	Adult/Pediatric	Adult/Pediatric/Infant/Neonate	Equivalent. Only adult and pediatric sensors are involved in this submission

Feature	Subject Device (Model: U403-254, U103-254, U103-125, U403-125)	Predicate Device (K142832)	Comparison to Predicate Device
Intended application site	Finger	Finger or toe	Equivalent. Only finger clip sensors are involved in this submission
Prescription or OTC	Rx Only	Rx Only	Identical
Use type	Reusable	Disposable/Reusable	Equivalent. Only reusable sensors are involved in this submission
Sensor Structure Composition	Sensor connector, cable, LED&PD, finger clip	Sensor connector, cable, LED&PD, adhesive tape/finger clip/soft tip	Equivalent. Only finger clip sensors are involved in this submission
Raw material	Cable: Copper conductor in PVC jacket LED wavelength: 660nm/905nm Patient-contacting material: ABS/Silicone	Cable: Copper conductor in PVC jacket LED wavelength: 660nm/905nm Patient-contacting material: ABS/Silicone	Identical
Performance (Arms)			
Saturation Accuracy, No Motion (70-100%)	±3%	±3%	Identical
Pulse Rate Accuracy, No Motion	±3 bpm (30-250 bpm)	±3 bpm (30-250 bpm)	Identical
Environmental			
Operating Temperature	5 to 40 °C	5 to 40 °C	Identical
Operational/Storage Humidity	10 to 85%	10 to 85%	Identical
Biocompatibility	Pass ISO 10993 cytotoxicity, skin	Pass ISO 10993 cytotoxicity, skin irritation and skin	Identical

Feature	Subject Device (Model: U403-254, U103-254, U103-125, U403-125)	Predicate Device (K142832)	Comparison to Predicate Device
	irritation and skin sensitivity tests	sensitivity tests	
Energy source	Monitor power supply	Monitor power supply	Identical

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 U403-125 versus arterial oxygen saturation (SaO₂) as determined by co-oximetry. 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 Finger Clip SpO₂ Sensors are as safe and effective and are substantially equivalent to the predicate devices.