April 14, 2026

Unimed Medical Supplies, Inc.
℅ Huanyu Zeng
RA Specialist
Unimed Medical Supplies Inc.
Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, Baoan District
Shenzhen, CHN 518108

Re: K260931
Trade/Device Name:
Unimed Reusable Finger Clip SpO2 Sensors (U403-49R and U103-49R)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 20, 2026
Received: March 20, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260931

Please provide the device trade name(s).

Unimed Reusable Finger Clip SpO2 Sensors (U403-49R and U103-49R) (U403-49R);
Unimed Reusable Finger Clip SpO2 Sensors (U403-49R and U103-49R) (U103-49R)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(K) Summary

1. Submitter

Date Prepared:	Mar. 20, 2026
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 Special 510(k).

2. Proposed Device

Trade Name:	Unimed Reusable Finger Clip SpO_2 Sensors (U403-49R and U103-49R)
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
K242580	Unimed Reusable Finger Clip SpO2 Sensors

4. Device description

The subject devices, Unimed Reusable Finger Clip SpO_2 Sensors, are fully compatible reusable sensors for use with monitor that incorporates Masimo technology. These sensors are supplied non-sterile.

The subject sensors consist of a plug/connector, a cable, and a patient-contacting (finger clip) with LED and photodetector.

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

Subject device	Compatible monitor
U403-49R	Masimo Radical 7
U103-49R	

Compared with the predicate devices (U403-125 and U103-125, cleared under K242580), the subject devices (U403-49R and U103-49R) have the following change:

- Change in interface connector only. All other specifications including LED, photodetector, and patient populations are identical to the predicate.

The purpose of this Special 510(k) submission is to receive clearance to market U403-49R and U103-49R, which differ from the predicate devices (K242580) only in connector type.

5. 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.

6. Comparison to predicate device

The subject devices, U403-49R and U103-49R, and the predicate devices, Unimed Reusable Finger Clip SpO2 Sensors (K242580), are compared in the following substantial equivalence table.

Feature	Subject Device (Model: U403-49R, U103-49R)	Predicate Device (K242580)	**Comparison to Predicate Device**
General Information			
Device name	Unimed Reusable Finger Clip SpO2 Sensors	Unimed Reusable Finger Clip SpO2 Sensors	Identical
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 SpO2 Sensors are indicated for continuous	Unimed Reusable Finger Clip SpO2 Sensors are indicated for continuous	Identical

Feature	Subject Device (Model: U403-49R, U103-49R)	Predicate Device (K242580)	**Comparison to Predicate Device**
	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.	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.	
Principle of operation	Two-wavelength relative optical absorption	Two-wavelength relative optical absorption	Same
Key performance specifications/ characteristics			
Intended patient population	Adult (>30 kg) / Pediatric (10-50 kg)	Adult (>30 kg) / Pediatric (10-50 kg)	Identical
Intended application site	Finger	Finger	Identical
Prescription or OTC	Rx Only	Rx Only	Identical
Use type	Reusable	Reusable	Identical
Sensor Structure Composition	DB9 connector, cable, LED & photodetector, finger clip	Card-edge connector, cable, LED & photodetector, finger clip	Different connector type only (DB9 vs. card-edge). All other components identical.
Raw material	Connector: DB9 connector Cable: Double-shielded copper conductor in TPU jacket LED: 660nm/905nm Finger clip: ABS Silicone pad: Biocompatible silicone	Connector: Card-edge connector Cable: Double-shielded copper conductor in TPU jacket LED: 660nm/905nm Finger clip: ABS Silicone pad: Biocompatible silicone	Equivalent
Performance (Arms)			

Feature	Subject Device (Model: U403-49R, U103-49R)	Predicate Device (K242580)	Comparison to Predicate Device
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 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

7. Verification and validation testing

Non-clinical test data

This submission is a Special 510(k). The proposed device change consists of a connector modification; the key electro-optical components and patient-contacting materials remain unchanged from the predicate device. Accordingly, biocompatibility and clinical performance evaluations were not repeated, as these assessments remain valid and applicable to the subject devices.

Non-clinical verification testing was conducted to confirm that the proposed connector change does not adversely affect device safety or performance and that the Unimed Reusable Finger Clip SpO_2 Sensors (models U403-49R and U103-49R) remain substantially equivalent to the predicate devices. Testing was performed in conformance with the following 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)

Verification testing addressed risks associated with the connector change, including electromagnetic compatibility, non-clinical SpO_2 and pulse rate performance (simulated use), mechanical durability (bending and drop), mechanical integrity (tensile strength), and electrical safety (dielectric strength). All tests passed their respective acceptance criteria, confirming that device safety and performance are maintained.

Biocompatibility

Biocompatibility evaluation was not repeated for this Special 510(k) submission. The patient-contacting components — the finger clip housing and silicone pad — are identical to those of the predicate device. These components involve contact with intact skin and are classified as prolonged exposure per ISO 10993-1:2018. Prior biocompatibility testing on the predicate device addressed all relevant endpoint assessments, including cytotoxicity (ISO 10993-5), skin sensitization (ISO 10993-10), and skin irritation (ISO 10993-23). As the patient-contacting materials are unchanged, this data remains applicable to the subject devices.

Clinical Performance Data

Clinical accuracy testing was not repeated for this Special 510(k) submission. The electro-optical components governing SpO_2 measurement accuracy are unchanged from the predicate device. The prior clinical study, conducted under an approved protocol with subject informed consent per ISO 80601-2-61 and FDA's Pulse Oximeter Guidance, demonstrated the accuracy of the U403-49R against arterial oxygen saturation (SaO_2) measured by CO-oximetry in human adult volunteers including a sufficient proportion of darkly pigmented subjects. This clinical data remains applicable to the subject devices.

8. Substantial Equivalence Statement

Based on the comparison, analysis, and the submitted verification and validation data, Unimed believes that the Unimed Reusable Finger Clip SpO_2 Sensors are as safe and effective and are substantially equivalent to the predicate devices.