February 20, 2025

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

Re: K243086
Trade/Device Name: Unimed Reusable Finger Clip SpO2 Sensors (UXXX-91 Series) (U403-91);
Unimed Reusable Finger Clip SpO2 Sensors (UXXX-91 Series) (U410-91);
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: January 20, 2025
Received: January 21, 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) 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

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)*

K243086

Device Name

Unimed Reusable Finger Clip SpO2 Sensors (UXXX-91 Series) (U403-91);
Unimed Reusable Finger Clip SpO2 Sensors (UXXX-91 Series) (U410-91)

Indications for Use *(Describe)*

Models: U403-91, U410-91
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. 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:

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*"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:** | Jan. 20, 2025 |
| **Submitter/Manufacturer:** | Unimed Medical Supplies Inc.<br>Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, Baoan District, Shenzhen, China 518108<br>FDA Establishment Number: 3007307487 |
| **Contact:** | Zeng Huanyu<br>RA Specialist<br>Tel: +86-755 26695165<br>E-mail: zenghy@unimed.cn |
| **510(k) Submission Type** | This is a traditional 510(k). |

## 2. Proposed Device

| | |
|---|---|
| **Trade Name:** | Unimed Reusable Finger Clip $SpO_2$ Sensors (UXXX-91 Series) |
| **Common Name:** | Oximeter Sensor |
| **Model Numbers** | U403-91, U410-91 |
| **Classification:** | Medical Specialty: Cardiovascular<br>Regulation: 21 CFR 870.2700 – Oximeter<br>Product Code: DQA<br>Class: II |

## 3. Predicate Device

| 510(K) No. | Trade Name |
|---|---|
| K062605 | Philips Reusable $SpO_2$ Sensor, Models M1196A and M1196T |

## 4. Device description

The subject devices, Unimed Reusable Finger Clip SpO2 Sensors (UXXX-91 Series), are fully compatible reusable sensors for use with Philips Itellivue MP30. These sensors are supplied non-sterile.

The subject sensors (Models: U403-91 and U410-91) consist of a plug/connector (Philips D8 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.

Patient-contacting materials of the subject sensors include ABS, silicone, and TPU, all of which have been qualified against biocompatibility requirements in ISO 10993-5, ISO 10993-10, and ISO 10993-23.

## 5. Intended use/Indications for use

Models: U403-91, U410-91

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. These devices are for prescription use only.

## 6. Comparison to predicate devices

| Feature | Subject Device (Model: U410-91, U403-91) | Predicate Device (K062605) | Comparison to Predicate Device |
|---|---|---|---|
| General Information | | | |
| Device name | Unimed Reusable Finger Clip $SpO_2$ Sensors (UXXX-91 Series) | Philips Reusable $SpO_2$ Sensor, Models M1196A and M1196T | / |
| Classification Regulation/ Product Code | 21 CFR 870.2700, Class II/DQA | 21 CFR 870.2700, Class II/DQA | Identical |
| Intended use/Indications for use | Models: U403-91, U410-91 Unimed Reusable Finger Clip SpO2 Sensors are indicated for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin ($SpO_2$) and | The M1196A and M1196T reusable Clip sensors provide continuous, non-invasive measurement of arterial oxygen saturation (pulse rate signal and plethysmograph wave) to any $SpO_2$ device that has passed validation | Substantially equivalent |

| Feature | Subject Device (Model: U410-91, U403-91) | Predicate Device (K062605) | Comparison to Predicate Device |
|---|---|---|---|
| | pulse rate (PR) for adult patients weighing greater than 30 kg. These devices are for prescription use only. | testing. Either sensor can be comfortably clipped onto the finger of patients weighing > 40 kg (typically adult patients). | |
| Principle of operation | Two-wavelength relative optical absorption | Two-wavelength relative optical absorption | Identical |
| Key performance specifications/ characteristics | | | |
| Intended patient population | Adults | Patients weighing > 40 kg (typically adult patients) | Substantially equivalent |
| Intended application site | Finger | Finger | Identical |
| Prescription or OTC | Rx Only | Rx Only | Identical |
| Use type | Reusable | Reusable | Identical |
| Sensor Structure Composition | Sensor connector, cable, LED&PD, finger clip | Sensor connector, cable, LED&PD, finger clip | Identical |
| Raw material | Sensor connector: Philips D Connect 8 pin connector. Cable: Copper conductor in TPU jacket. LED wavelength: 663 nm/890 nm Patient-contacting material: ISO10993-compliant | Sensor connector: Philips D Connect 8 pin connector. Cable: Copper conductor in TPU jacket. LED wavelength: ~660 nm/~890 nm Patient-contacting material: ISO10993-compliant | Substantially equivalent |
| Performance (Arms) | | | |
| Saturation Accuracy, No Motion | ±3% (70-100%) | ±3% (70-100%) | Identical |
| Pulse Rate Accuracy, No Motion | ±3 bpm (30-250 bpm) | ±2% or 1 bpm, whichever is greater | Substantially equivalent[1] |

| Feature | Subject Device (Model: U410-91, U403-91) | Predicate Device (K062605) | Comparison to Predicate Device |
|---|---|---|---|
| | | (30 to 300 bpm) | |
| Low Perfusion Accuracy | $SpO_2$ ±3% (70-100%) | $SpO_2$ ±3% (70-100%) | Identical |
| | Pulse ±3 bpm (30-250 bpm) | Pulse ±2% or 1 bpm, whichever is greater (30 to 300 bpm) | Substantially equivalent[1] |
| Environmental | | | |
| Operating Temperature | 5 to +40 °C | 0 to 40 °C (32 to 104 °F) | Substantially equivalent |
| Operational/Storage Humidity | 10-85% | 15 to 90% | 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. 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. 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 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 80601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- 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

## 8. Clinical test data

Clinical studies were 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 ($SaO_2$) 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.

## 9. Substantial Equivalence Statement

Based on the comparison, analysis, and the submitted non-clinical and clinical data, Unimed believes that the Unimed Reusable Finger Clip $SpO_2$ Sensors (UXXX-91 Series) are as safe and effective and are substantially equivalent to the predicate devices.