December 19, 2022

Unimed Medical Supplies, Inc.
Hui Zhang
General Manager
Bld#8, Nangang 3rd Industrial Park Tangtou, Shiyan
Shenzhen, Guangdong 518108
China

Re: K222213
Trade/Device Name: Pulse Oximeter (UC-200, UC-201, UC-202, UC-203, UC-204, UC-100, UC-101, UC-102, UC-103, UC-104)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 10, 2022
Received: November 10, 2022

Dear Hui Zhang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

James J. Lee -S

James J. Lee, Ph.D.
Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222213

Device Name
Pulse Oximeter

Indications for Use *(Describe)*
The pulse oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric (≥10Kg) patients during both no motion and motion conditions, and for patients who are well or poorly perfused.
Pulse Oximeter is intended for hospitals, hospital-type facilities, home environments.

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.

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510(k) Summary

In accordance with 21 CFR 807.92 the 510(k) Summary for the Unimed pulse oximeters are provided below.

1. SUBMITTER

Applicant: Unimed Medical Supplies, Inc.
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Shenzhen Guangdong, CHINA 518108
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E-mail: FrankZhang@unimed.cn

Date Prepared: June 24, 2022

2. DEVICE

510(k) Number: K222213

Device Trade Name: Pulse Oximeter (including UC-200, UC-201, UC-202, UC-203, UC-204, UC-100, UC-101, UC-102, UC-103, UC-104)

Classification Name: 21 CFR 870.2700, Oximeter

Regulatory Class: Class II

Product Code, Panel: DQA, Anesthesiology

Reason for Submission: New Application. No prior submission associated with the current submission.

Predicate Device: Narig Bio-Medical Pulse Oximeter, K211632

3. DEVICE DESCRIPTION

The Pulse Oximeter is a small, lightweight, portable, reusable, digit pulse oximeter that displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR) and perfusion index (PI) by measuring the absorption of red and infrared light passing through perfused tissue. It indicated for adult and pediatric (≥10Kg) patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

The device consists of probe, electronic circuits, OLED/LED display (differentiated by models) and plastic housing which powered by two alkaline AAA batteries.

The function difference of models is listed as follows:

Function Difference of Models

Abbreviation description:

- sup: support function
- opt: optional function
- n/a: disable/not support function

Function	UC-200	UC-201	UC-202	UC-203	UC-204	UC-100	UC-101	UC-102	UC-103	UC-104
Display Type	OLED	OLED	OLED	OLED	OLED	LED	LED	LED	LED	LED
Key Function	sup	sup	sup	sup	sup	sup	sup	sup	sup	sup
Automatic Shut-Down	sup	sup	sup	sup	sup	sup	sup	sup	sup	sup
Low Power Tip	sup	sup	sup	sup	sup	sup	sup	sup	sup	sup
Low Power Shut-Down	sup	sup	sup	sup	sup	sup	sup	sup	sup	sup
Display Light Intensity	opt	opt	opt	opt	opt	opt	opt	opt	opt	opt
Direction Rotation	opt	opt	opt	opt	opt	n/a	n/a	n/a	n/a	n/a
SpO_2 Parameter	sup	sup	sup	sup	sup	sup	sup	sup	sup	sup
Pulse Parameter	sup	sup	sup	sup	sup	sup	sup	sup	sup	sup
Perfusion Parameter	opt	opt	opt	opt	opt	opt	opt	opt	opt	opt
Bargraph	sup	sup	sup	sup	sup	sup	sup	sup	sup	sup
Plethysmogram	sup	sup	sup	sup	sup	n/a	n/a	n/a	n/a	n/a
Battery Display	sup	sup	sup	sup	sup	n/a	n/a	n/a	n/a	n/a
User Menu Setup	opt	opt	opt	opt	opt	n/a	n/a	n/a	n/a	n/a
Trend Graph	opt	opt	opt	opt	opt	n/a	n/a	n/a	n/a	n/a

4. INTENDED USE/INDICATIONS FOR USE

The pulse oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric (≥10Kg) patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

Pulse Oximeter is intended for hospitals, hospital-type facilities, home environments.

5. SUBSTANTIAL EQUIVALENCE

Device Specification

The pulse oximeter specifications are as follows:

Feature	Specification	Models
Display		
Display Range	Oxygen Saturation (SpO_2): 0-100%	All models
	Pulse Rate (PR): 25-250 beats per minute (BPM)	All models
	Perfusion Index (PI): 0.02-20%	All models
Display Waveform	Plethysmogram	UC-200/ UC-201/ UC-202/ UC-203/ UC-204
	Bargraph	All models
Display Resolution	SpO_2: 1%	All models
	PR: 1 BPM	
Measurement Accuracy in Accordance with ISO80601-2-61		
SpO_2, No Motion	70 – 100%, 2%, ARMS, adults/pediatrics	All models
SpO_2, Motion	70 – 100%, 3% ARMS, adults/pediatrics	All models
SpO_2, Low Perfusion	70 – 100%, 2%, ARMS, adults/pediatrics	UC-200/ UC-100
Pulse Rate, No Motion	25 – 250 BPM, 2 BPM ARMS, adults/pediatrics	All models
Pulse Rate, Motion	25 – 250 BPM, 4 BPM ARMS, adults/pediatrics	All models
Pulse Rate, Low Perfusion	25 – 250 BPM, 2 BPM ARMS, adults/pediatrics	UC-200/ UC-100
Power		
Internal battery	Alkaline “AAA” batteries	All models

Mechanical		
Enclosure Material	Plastic	All models
Dimensions/Weight	62mm × 35mm × 31mm	All models
Weight	Less than 75g (contain battery)	All models
Environmental		
Operating Temperature	0°C to +40°C, ambient humidity	All models
Storage Temperature	-20°C to +60°C, ambient humidity	All models
Operating/Storage Humidity	15% to 95%, non-condensing	All models
Atmospheric Pressure	79.5kPa~107.4kPa	All models
Mode of Operation		
Mode of Operation	Spot Check	All models

In conclusion, the minor differences of the models do not change the fundamental intended use of the pulse oximeter.

Technological Comparison

The table below compares the key technological feature of the subject devices to the predicate device (the Narig Bio-Medical's Pulse Oximeter, K211632).

Item	Predicate Devices(K211632)	Subject Devices	Comparison
Display			
Display Type	OLED display (FRO-200, FRO-201, FRO-202, FRO-203, FRO-204) LED display (FRO-100, FRO-101, FRO-102, FRO-103, FRO-104)	OLED display (UC-200, UC-201, UC-202, UC-203, UC-204) LED display (UC-100, UC-101, UC-102, UC-103, UC-104)	Different
Display Range	Oxygen Saturation (SpO_2): 0-100%	Oxygen Saturation (SpO_2): 0-100%	Same
	Pulse Rate (PR): 25-250 beats per minute (BPM)	Pulse Rate (PR): 25-250 beats per minute (BPM)	Same
	Perfusion Index (PI): 0.02-20%	Perfusion Index (PI): 0.02-20%	Same
Display Waveform	Plethysmogram (FRO-200, FRO-201, FRO-202, FRO-203, FRO-204)	Plethysmogram (UC-200/ UC-201/ UC-202/ UC-203/ UC-204)	Same
	Bargraph	Bargraph	Same
Display Resolution	SpO_2: 1%	SpO_2: 1%	Same
	PR: 1 BPM	PR: 1 BPM	Same
Measurement Accuracy in Accordance with ISO80601-2-61			

SpO_2, No Motion	70 - 100%, 2%, A_{RMS}, adults/pediatrics	70 - 100%, 2%, A_{RMS}, adults/pediatrics	Same
SpO_2, Motion	70 - 100%, 3% A_{RMS}, adults/pediatrics	70 - 100%, 3% A_{RMS}, adults/pediatrics	Same
SpO_2, Low Perfusion	Only for ***FRO-200 / FRO-100*** 70 - 100%, 2%, A_{RMS}, adults/pediatrics	Only for ***UC-200 / UC-100*** 70 - 100%, 2%, A_{RMS}, adults/pediatrics	Different
Pulse Rate, No Motion	25 - 250 BPM, 2 BPM A_{RMS}, adults / pediatrics	25 - 250 BPM, 2 BPM A_{RMS}, adults / pediatrics	Same
Pulse Rate, Motion	25 - 250 BPM, 4 BPM A_{RMS}, adults / pediatrics	25 - 250 BPM, 4 BPM A_{RMS}, adults / pediatrics	Same
Pulse Rate, Low Perfusion	Only for ***FRO-200/ FRO-100*** 25 - 250 BPM, 2 BPM A_{RMS}, adults / pediatrics	Only for ***UC-200/ UC-100*** 25 - 250 BPM, 2 BPM A_{RMS}, adults / pediatrics	Different
Power			
Internal battery	Alkaline “AAA” batteries	Alkaline “AAA” batteries	Same
Mechanical			
Enclosure Material	Plastic	Plastic	Same
Dimensions/Weight	62mm × 35mm × 31mm	62mm × 35mm × 31mm	Same
Weight	Less than 75g (contain battery)	Less than 75g (contain battery)	Same
Environmental			
Operating Temperature	0°C to +40°C, ambient humidity	0°C to +40°C, ambient humidity	Same
Storage Temperature	-20°C to +60°C, ambient humidity	-20°C to +60°C, ambient humidity	Same
Operating/Storage Humidity	15% to 95%, non-condensing	15% to 95%, non-condensing	Same
Atmospheric Pressure	79.5kPa-107.4kPa	79.5kPa-107.4kPa	Same
Mode of Operation			
Mode of Operation	Spot Check	Spot Check	Same
Compliance Standards			
Bio-compatibility	ISO 10993-1 ISO 109903-5 ISO 10993-10	ISO 10993-1 ISO 109903-5 ISO 10993-10	Same
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Performance	ISO 80601-2-61	ISO 80601-2-61	Same

As seen in the comparison tables, the subject and predicate devices have same design principle, same design features and performance specifications. In conclusion, the different technological characteristics between the subject and predicate devices will not impact the substantial equivalence.

6. PERFORMANCE DATA

The devices and the predicate are identical devices. The predicate devices have been conducted functional and system level test. The functional and system level testing showed that the devices continue to meet specifications and meets relevant consensus standards.

Biocompatibility Testing

The devices and the predicate are identical devices. Testing of the predicate devices have been completed per FDA's "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" guidance document and the requirements of ISO 10993-1:2018.

Software Verification and Validation Testing

The predicate devices were tested for Software verification and validation, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Verification of the pulse oximeter was conducted to ensure that the product works as designed. Validation was conducted to check the design and performance of the product.

Electromagnetic Compatibility and Electrical Safety

The pulse oximeter was assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.
- IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 62471: 2006 Photobiological Safety of Lamps and Lamp Systems.

Bench Testing

The device and the predicate are identical devices. The predicate devices have been conducted functional and system level testing. The results of the bench testing show that the subject device meets its accuracy specification and meet relevant consensus standards.

- IEC 60601-1-6:2010, AMD1:2013 Medical electrical equipment-part 1-6: general requirements for basic safety and essential performance- collateral standard: usability.
- IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices.
- ISO 80601-2-61:2011 Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment.
- EN ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.

Cleaning Validation

Cleaning and disinfection validation testing of the predicate devices were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling". The test results meet relevant standards.The device and the predicate are identical devices.

Clinical Data

Clinical testing of the predicate devices have shown that pulse oximeters meet relevant consensus standards.

- ISO 80601-2-61:2017 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

7. SUBSTANTIAL EQUIVALENCE CONCLUSION

The subject and predicate devices are exactly the same. The pulse oximeter is identical to the cleared version and is not modified. Therefore, the subject device is substantially equivalent to the predicate device.