January 14, 2022

Shenzhen Narig Bio-Medical Technology Co., Ltd.
Fei Han
General Manager
1106 Room, East Tower, Digital Culture Industry Base
No.10128 Shennan Road, Nanshan District
Shenzhen, Guangdong 518052
China

Re: K211632
Trade/Device Name: Pulse Oximeter (FRO-200, FRO-201, FRO-202, FRO-203, FRO-204, FRO-100, FRO-101, FRO-102, FRO-103, FRO-104)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 16, 2021
Received: December 16, 2021

Dear Fei Han:

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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K211632

Device Name
Pulse Oximeter
(Include FRO-200, FRO-201, FRO-202, FRO-203, FRO-204, FRO-100, FRO-101, FRO-102, FRO-103, FRO-104)

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.**

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
*PRAStaff@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."*

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

## 1. SUBMITTER

Applicant: Shenzhen Narig Bio-Medical Technology Co., Ltd.
1106 Room, East Tower, Digital Culture Industry Base
No.10128 Shennan Road, Nanshan District
518052, Shenzhen, P.R. China
Tel: +86 755-86566930

Contact: Contact Person: Fei Han
Title: General Manager
Phone: +86 158 2078 2640
Tel: +86 755-86566930
E-mail: Martial.Han@narigmed.com

Date Prepared: April 24, 2021

## 2. DEVICE

| | |
|---|---|
| Device Trade Name: | Pulse Oximeter (including FRO-200, FRO-201, FRO-202, FRO-203, FRO-204, FRO-100, FRO-101, FRO-102, FRO-103, FRO-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: | Masimo Corporation<br>MightySat™ Pulse Oximeter, K181956 |

## 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 ($SpO_2$), 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 | FRO-200 | FRO-201 | FRO-202 | FRO-203 | FRO-204 | FRO-100 | FRO-101 | FRO-102 | FRO-103 | FRO-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 | FRO-200/ FRO-201/ FRO-202/ FRO-203/ FRO-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 | FRO-200/ FRO-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 | FRO-200/ FRO-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 Masimo’s Pulse Oximeter, K181956).

| Item | Predicate Devices(K181956) | Subject Devices | Comparison |
|---|---|---|---|
| **Display** | | | |
| Display Type | OLED color display | OLED display (FRO-200, FRO-201, FRO-202, FRO-203, FRO-204) | Different |

| | | | |
|---|---|---|---|
| | | LED display (FRO-100, FRO-101, FRO-102, FRO-103, FRO-104) | |
| Display Range | Oxygen Saturation ($SpO_2$): 0-100% | Oxygen Saturation ($SpO_2$): 0-100% | Same |
| | Pulse Rate (PR): 25-240 beats per minute (BPM) | Pulse Rate (PR): 25-250 beats per minute (BPM) | Different |
| | Perfusion Index (PI): 0.02-20% | Perfusion Index (PI): 0.02-20% | Same |
| | Pleth Variability Index (PVI): 0-100% | N/A | Different |
| | Respiration rate (RR): 4-70 respirations per minute (RPM) | N/A | Same |
| Display Waveform | Plethysmogram | Plethysmogram (FRO-200/ FRO-201/ FRO-202/ FRO-203/ FRO-204) | Same |
| | Signal IQ | Bargraph | Different |
| Display Resolution | $SpO_2$: 1% | $SpO_2$: 1% | Same |
| | PR: 1 BPM | PR: 1 BPM | Same |
| | RR: 1 RPM | N/A | Different |
| **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 | 70 - 100%, 2%, $A_{RMS}$, adults/pediatrics | Only for ***FRO-200 / FRO-100***<br>70 - 100%, 2%, $A_{RMS}$, adults/pediatrics | Same |
| Pulse Rate, No Motion | 25 - 240 BPM, 2 BPM $A_{RMS}$, adults / pediatrics | 25 - 250 BPM, 2 BPM $A_{RMS}$, adults / pediatrics | Different |
| Pulse Rate, Motion | 25 - 240 BPM, 5 BPM $A_{RMS}$, adults / pediatrics | 25 - 250 BPM, 4 BPM $A_{RMS}$, adults / pediatrics | Different |
| Pulse Rate, Low Perfusion | 25 - 240 BPM, 3 BPM $A_{RMS}$, adults / pediatrics | Only for ***FRO-200/ FRO-100***<br>25 - 250 BPM, 2 BPM $A_{RMS}$, adults / pediatrics | Different |
| RRp | 4 - 70 RPM, 3 RPM $A_{RMS}$, 1 RPM Mean Error, adults | N/A | Different |
| **Power** | | | |
| Internal battery | Alkaline "AAA" batteries | Alkaline "AAA" batteries | Different |
| **Interface** | | | |
| Wireless | Bluetooth LE | N/A | Different |
| **Mechanical** | | | |
| Enclosure Material | Plastic | Plastic | Same |
| Dimensions/Weight | 2.9'' ×1.6'' ×1.2''<br>(7.4cm×4.1cm×3.0cm) | 62mm × 35mm × 31mm | Different |
| Weight | 0.16lbs (73g) | Less than 75g(contain battery) | Different |
| **Environmental** | | | |
| Operating Temperature | 5°C to +40°C, ambient humidity | 0°C to +40°C, ambient humidity | Different |
| Storage Temperature | -40°C to +70°C, ambient humidity | -20°C to +60°C, ambient humidity | Different |
| Operating/Storage Humidity | 10% to 95%, non-condensing | 15% to 95%, non-condensing | Different |
| Atmospheric Pressure | 540 mBar to 1060 mBar | 79.5kPa-107.4kPa | Different |
| **Mode of Operation** | | | |
| Mode of Operation | Spot Check | Spot Check | Different |
| **Compliance Standards** | | | |
| Bio-compatibility | ISO 10993-1<br>ISO 109903-5<br>ISO 10993-10 | ISO 10993-1<br>ISO 109903-5<br>ISO 10993-10 | Same |
| Electrical Safety | IEC 60601-1<br>IEC 60601-1-11 | IEC 60601-1<br>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, similar 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

To establish the substantial equivalence of the pulse oximeter, Narigmed conducted functional and system level testing on the subject device. The testing provided an evaluation of the performance of the device relevant to each of the differences between the subject device and the predicate device. The functional and system level testing showed that the devices continue to meet specifications and the performance of the device is equivalent to the predicate.

Narigmed has conducted testing to ensure the subject device meets relevant consensus standards.

## Biocompatibility Testing

Testing of the pulse oximeter has 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

Software verification and validation testing was conducted 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

To establish the substantial equivalence of the pulse oximeter, Narigmed conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its accuracy specification, and is substantially equivalent to the predicate device.

In addition, Narigmed has conducted testing to ensure the subject devices 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 was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

## Clinical Data

Narigmed provided the results of clinical testing to demonstrate that pulse oximeter meets 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. CONCLUSION

Based on the detailed comparison of specifications for each of the modifications to the previously cleared devices (K181956), the performance testing and conformance with applicable standards, the pulse oximeter (including FRO-200, FRO-201, FRO-202, FRO-203, FRO-204, FRO-100, FRO-101, FRO-102, FRO-103, FRO-104) can be found substantially equivalent to the predicate devices.