November 13, 2024

Nonin Medical Inc.
% Sheila Mena
Sr Regulatory Affairs Specialist
13700 1st Ave N
Plymouth, MN 55441

Re: K211498
Trade/Device Name: Nonin OTC Pulse Oximeter Model 3250
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: OLK
Dated: May 21, 2024
Received: May 21, 2024

Dear Shiela Mena:

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.

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.

510(k) Number *(if known)*
K211498

Device Name

Nonin Medical 3250 Finger Pulse Oximeter

Indications for Use *(Describe)*

The Nonin Medical 3250 Finger Pulse Oximeter is a small, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of individuals who are well or poorly perfused under no motion conditions for medical use without a prescription. It is intended for spot-checking of individuals 18 years and older with finger thickness between 0.8-2.5 cm (0.3-1.0 inch). It is not intended for the diagnosis or screening of lung disease, for use in treatment decisions, and should only be used for making healthcare decisions under the advice of a healthcare provider.

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.

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5.0 TRADITIONAL 510(K) SUMMARY

Submitted by:	Nonin Medical, Inc. 13700 1st Ave North Plymouth, MN 55441
Contact Person:	Sheila Mena Sr Regulatory Affairs Specialist 13700 1st Ave N Plymouth, MN 55441
Date of Summary:	October 8, 2024
Device Trade Name:	Nonin Model 3250 OTC Pulse Oximeter (K211498)
Common or Usual Name:	Pulse Oximeter
Classification Name:	Oximeter
Class:	2
Product Code:	OLK
Review Panel:	Anesthesiology
Predicate Device(s):	Masimo MightySat OTC Medical (K214115)
Reference Device	Nonin's Model 3230 finger pulse oximeter (K131021)
Model Number(s):	3250

Device Description:	Model 3250 Pulse Oximeter is a small, lightweight, portable, battery operated, digit pulse oximeter that displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate and is intended for over-the-counter use. The device measures the absorption caused by the pulsation of blood in the vascular bed, which are used to determine oxygen saturation and pulse rate. Light emitting diodes (LEDs) are contained within the device along with the photo detector, which is on the opposite side of the probe from the LEDs. The SpO_2 and pulse rate are displayed on the LCD display of the device. The LCD also provides a visual indication of the pulse signal, while blinking at the corresponding pulse rate. The display will indicate poor pulse quality that may affect the readings. All associated electronics and the microcontrollers are within the sensor, which is activated by inserting a patient's digit. This simple operation activates the internal circuitry automatically upon application. The Model 3250 includes a Bluetooth radio to send real time oximeter readings to a host device. The Model 3250 features a Bluetooth LE version 4.0 radio to ease the connectivity setup configuration with options to implement secure connections for the point-to-point data connection. This oximeter uses ISP3, Nonin's core signal processing technology software.
Indication for Use:	The Nonin Medical 3250 Finger Pulse Oximeter is a small, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of individuals who are well or poorly perfused under no motion conditions for medical use without a prescription. It is intended for spot-checking of individuals 18 years and older with finger thickness between 0.8-2.5 cm (0.3-1.0 inch). It is not intended for the diagnosis or screening of lung disease, for use in treatment decisions, and should only be used for making healthcare decisions under the advice of a healthcare provider.

Technological Characteristics/Substantial Equivalence Rationale:

The Model 3250 Pulse Oximeter is designed and built identical to the reference device, Model 3230 Pulse Oximeter.

- Nonin oximeters utilize the same oximeter technology thus the accuracy of Model 3250 is identical to the results of the reference device, Model 3230.
- Nonin oximeters use the same electro-optical sensor components, and the

SpO_2 algorithm of Model 3250 is identical to the reference device, Model 3230.

- The Bluetooth radio module of Model 3250 is the same technology presented in the reference device, Model 3230.
- Nonin's Model 3250 Pulse Oximeters are made from the same materials, have the same design, and the manufacturing process as the reference device.

The Model 3250 Pulse Oximeter and the reference device, Model 3230 Pulse Oximeter, have a different indication for use, intended use, and labeling.

- The Model 3250 Pulse Oximeter is intended for over-the-counter use.

The Model 3250 Pulse Oximeter Indications for use are similar to the predicate device, Masimo MightySat OTC Medical.

- Nonin model 3250 is equivalent to the predicate device regarding the OTC indication.
- Nonin model 3250 is equivalent to the predicate device regarding measures, patient population age group, patient use conditions, and environmental attributes. Further specification is provided compared to the predicate and reference devices with respect to physical attributes.
- Nonin model 3250 is similar to the predicate device regarding the device specifications.

Non-Clinical Performance Testing:

Nonin's Model 3250 Oximeter is supported by both laboratory and clinical hypoxia accuracy testing in order to ensure that it has appropriate performance, functional features to fully comply with ISO 80601-2-61:2017, and IEC 60601-1-11 collateral standard for home healthcare equipment.

Nonin's Model 3250 Oximeter complies with the following standards:

- ISO 10993-1:2018- Biological evaluation of medical devices Part 1: Evaluation and testing.
- IEC 60601-1-2:2014- Medical electrical equipment— Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-1-6:2013 - Medical Electrical Equipment – General requirements for basic safety and essential performance – Usability.
- 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.
- ISO 80601-2-61:2017 - Medical electrical equipment-particular requirements for basic safety and essential performance of pulse oximeter equipment.
- ANSI AAMI IEC 62304:2006/A1:2016 - Medical device software - Software life cycle processes

Clinical Data:
Performance clinical testing for pulse oximeter accuracy and usability testing participation by users is identical to the predicate device in 510(k) K131021.

To support the performance of the Model 3250, clinical data is provided as part of this submission.

The clinical performance testing included data from an independent study by Leeb and an internal study conducted at UCSF using Nonin's Model 9590. The optical path and algorithm for the Model 3250 is equivalent to the Model 9590. Therefore, the data from these two studies can be used to substantiate the Model 3250. The results support similar performance across all skin pigmentation.

In the Leeb study, there were 34 participants with diverse skin pigmentation utilizing a controlled desaturation study with arterial oxygen saturation (SaO2) plateaus between 70% and 100%. Skin pigmentation was assessed subjectively using a perceived Fitzpatrick Scale (pFP) and objectively using the individual typology angle (ITA) via spectrophotometry at nine anatomical sites.

%SaO2	70 - 80%			80 - 90%			90 - 100%			70 – 100%
Skin Pigmentation	Light	Medium	Dark	Light	Medium	Dark	Light	Medium	Dark	
ARMS	**1.8**	**1.7**	**2.3**	**1.2**	**2.2**	**1.5**	**1.4**	**2.9**	**2**	**2**
BIAS	**0.5**	**0.9**	**2**	**0**	**1.1**	**0.8**	**0.1**	**0.2**	**-0.2**	**0.6**

In the UCSF study, there were 26 participants with diverse skin pigmentation utilizing a controlled desaturation study with arterial oxygen saturation (SaO2) plateaus between 70% and 100%. Skin pigmentation as assessed subjectively using both Fitzpatrick Scale and Monk Scale, and objectively using the individual typology angle (ITA) via spectrophotometry using five anatomical sites.

%SaO2	70 - 80%	80 - 90%	90 - 100%	70 – 100%
ARMS	**1.56**	**1.86**	**2.85**	**2.27**

%SaO2	70 - 85%			85 - 100%		
Skin Pigmentation	Light	Medium	Dark	Light	Medium	Dark
BIAS	**1.9**	**1.14**	**2.57**	**0.98**	**0.43**	**1.08**

The result of the clinical testing supports the performance of the subject device, Model 3250, across all skin pigmentation. The subject device demonstrated equitable performance for the intended user population across all skin pigmentation sub-groups and the accuracy was within 3.0% ARMS guidance, without any clinically significant bias compared to the blood reference SaO2, or between the groups.

Usability of the reference device Model 3230 is used to substantiate usability of the Model 3250 OTC. Self-selection of an OTC device is substantiated by similar indications for use to the predicate device MightySat OTC. To further support OTC use, updates were included in the 3250 OTC IFU.

Conclusion: Nonin's Model 3250 is substantially equivalent to Masimo MightySat under K214115 supports the OTC indication of the 3250 and does not raise new questions of safety and effectiveness. In addition, the reference device Nonin's Model 3230 finger pulse oximeter cleared by the FDA under K131021 on 9/11/2013, supports the indications for use and labeling for Model 3250.