October 12, 2023

Masimo Corporation
Linus Park
Vice President, Regulatory
52 Discovery
Irvine, CA 92618

Re: DEN200076
Trade/Device Name: ORi
Regulation Number: 21 CFR 870.2720
Regulation Name: Hyperoxia monitoring device adjunct to pulse oximetry
Regulatory Class: Class II
Product Code: QWE
Dated: December 18, 2020
Received: December 21, 2020

Dear Linus Park:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ORi, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The ORi feature is intended to be used in patients undergoing surgery as an adjunct to SpO2 for increased monitoring resolution of elevated hemoglobin oxygen saturation levels (e.g., due to the administration of supplemental oxygen).
>
> The ORi feature is indicated for the monitoring of hemoglobin oxygen saturation levels in patients 18 years and older (adults and transitional adolescents) on supplemental oxygen during no-motion conditions perioperatively in hospital environments.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ORi, and substantially equivalent devices of this generic type, into Class II under the generic name hyperoxia monitoring device adjunct to pulse oximetry.

FDA identifies this generic type of device as:

> Hyperoxia monitoring device adjunct to pulse oximetry: A hyperoxia monitoring device adjunct to pulse oximetry is a device that monitors elevated hemoglobin oxygen saturation levels as an adjunct to arterial oxygen saturation monitoring.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act.
On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 21, 2020, FDA received your De Novo requesting classification of the ORi. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ORi into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the ORi can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Inaccurate measurement of hyperoxia or hypoxia leading to escalation of unneeded therapy and false reassurance	Clinical performance testing
Incorrect or delayed treatment due to over-reliance on device output for clinical decision-making without using arterial blood gas values for confirmation	Clinical performance testing Human factors/usability testing Labeling
Procedure delay or inaccuracy due to software failure or corruption in data transfer	Software verification, validation, and hazard analysis
Patient or operator injury due to electrical hazards	Electrical safety testing Electromagnetic compatibility testing
Adverse tissue reaction	Biocompatibility evaluation
Inaccurate measurement or infection due to unclean surfaces	Reprocessing validation Labeling

In combination with the general controls of the FD&C Act, the hyperoxia monitoring device adjunct to pulse oximetry is subject to the following special controls:

(1) Clinical performance testing under anticipated conditions of use must evaluate the accuracy of hyperoxia monitoring by the device and evaluate all adverse events.

(2) Human factors/usability testing must demonstrate that the user can correctly use the device, based solely on reading the instructions for use.

(3) Performance data must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance testing must validate the reprocessing instructions for the device, including demonstration of device performance after repeated cleaning and disinfection.

(6) Software verification, validation, and hazard analysis must be performed. Performance testing must demonstrate compatibility with pulse oximeter devices labeled to be compatible with the device.

(7) Labeling must include:
- (i) Cleaning and disinfection instructions;
- (ii) A summary of the clinical performance testing with the device;
- (iii) A warning against over-reliance on device output without using arterial blood gas values for confirmation; and
- (iv) Instructions to monitor oxygen delivery and patient clinical/cardiovascular status when device output changes.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the hyperoxia monitoring device adjunct to pulse oximetry they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Annie Abraham at 240-402-5219.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health