August 29, 2020

Masimo Corporation
Sindura Penubarthi
Regulatory Affairs Manager
52 Discovery
Irvine, California 92618

Re: K201432
Trade/Device Name: Masimo O3 Regional Oximeter System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: May 29, 2020
Received: June 1, 2020

Dear Sindura Penubarthi:

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,

Colin Kejing Chen
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201432

Device Name
Masimo O3 Regional Oximeter System

Indications for Use *(Describe)*

The non-invasive Masimo O3® Regional Oximeter System and accessories are indicated for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood (rSO2) in the tissue under the sensors in patients in healthcare environments. The O3® Regional Oximeter is only to be used with Masimo O3 sensors. The use of any other sensor is not supported or recommended by Masimo and could give erroneous results.

When used with the O3 Adult Sensor, the O3® Regional Oximeter is indicated for measuring absolute and trending regional hemoglobin oxygen saturation of blood (rSO2) on cerebral sites and trending rSO2 on non-cerebral sites in adults ≥ 40kg.

When used with the O3 Pediatric Sensor, the O3® Regional Oximeter is indicated for measuring absolute and trending regional hemoglobin oxygen saturation of blood (rSO2) on cerebral sites and trending rSO2 on non-cerebral sites in pediatrics ≥ 5 kg and < 40 kg.

When used with the O3 Neonatal Sensor, the O3® Regional Oximeter is indicated for measuring only trending regional hemoglobin oxygen saturation of blood (rSO2) on cerebral sites and trending rSO2 on non-cerebral sites in neonates < 10kg.

The ΔcHb, ΔO2Hb, ΔHHb provided as part of the Masimo O3 are indicated for the monitoring of the relative hemoglobin changes of oxygenated hemoglobin (ΔO2Hb), deoxygenated hemoglobin (ΔHHb), and total hemoglobin (ΔcHb) as measured from the Masimo O3 sensor when applied to the cerebral tissue in adults.

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

K201432

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7541 FAX: (949) 297-7592
Date:	August 29, 2020
Contact:	Sindura Penubarthi Regulatory Affairs Manager
Trade Name:	Masimo O3 Regional Oximeter System
Common Name:	Oximeter, Tissue Saturation
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/ MUD
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Expanded indications for use
Predicate Device:	K182429 – Masimo O3 Regional Oximeter System
Reference Predicate	K091224 – Somanetics INVOS 5100C K112820 – CAS Medical ForeSight Elite K113215 – Nonin Medical Model 7600 K162117 – NIRO-200NX
Performance Standards	There are no performance standards pursuant to Section 514 of the Food, Drug and Cosmetic Act for the above device.

1. Device Description

The Masimo O3 Regional Oximeter is a noninvasive regional oximeter designed to continuously measure and monitor regional hemoglobin oxygen saturation under the sensor. The Masimo O3 Regional Oximeter consists of the following components: O3 Module, O3 Sensors (e.g. O3 Adult, O3 Pediatric, and O3 Infant/Neonatal Sensors), and a display monitor (e.g. Root) same as those cleared under K182429.

The O3 System provides the following key measurements:

- *Regional Oxygenation (rSO_2):* Regional tissue oxygenation level in the deep tissue local to the sensor site.

MASIMO CORPORATION
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510(k) Summary

K201432

- *Delta Baseline (Δbase):* Relative difference in rSO_2 with respect to baseline rSO_2.
- *Area Under the Limit (AUL index):* Index that quantifies the duration (amount of time) the patient stays below rSO_2 low alarm limit and depth (refers to the gap between the patient's rSO_2 level and the rSO_2 low alarm limit) of patient's stay below the user-defined rSO_2 low alarm limit (LAL)
- *Delta Sp*O_2 *(ΔSp*O_2*)*: The difference between SpO_2 and rSO_2. The source of SpO_2 is from peripheral SpO_2 measurement (using pulse oximeter).
- *Delta HHb (ΔHHb):* a measure of the relative change in deoxygenated hemoglobin.
- *Delta* O_2*Hb (Δ*O_2*Hb)*: a measure of the relative change in the oxygenated hemoglobin.
- *Delta cHb (ΔcHb):* the sum of the Delta HHbi and Delta O_2Hbi, as a measure of the relative change in the total hemoglobin.

The performance specifications are included in table below:

Table 5.1.1

O3 Regional Oximeter System Specifications	
Feature	**Specification**
Performance (Arms)	
Non-Cerebral Oxygen Monitoring	
rSO_2 Trending (Adult, Pediatric, and Neonate)	3% for $SavO_2$ of 45%-85%
Cerebral Oxygen Monitoring	
rSO_2 Absolute (Adult ≥ 40 kg)	4% for $SavO_2$ of 45%-85%
rSO_2 Absolute (Pediatric ≥ 5 kg and < 40 kg)	5% for $SavO_2$ of 45%-85%
rSO_2 Trending (Adult, Pediatric, and Neonate)	3% for $SavO_2$ of 45%-85%

2. Intended Use/ Indications For Use

The non-invasive Masimo O3® Regional Oximeter System and accessories are indicated for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood (rSO_2) in the tissue under the sensors in patients in healthcare environments. The O3® Regional Oximeter is only to be used with Masimo O3 sensors. The use of any other sensor is not supported or recommended by Masimo and could give erroneous results.

When used with the O3 Adult Sensor, the O3® Regional Oximeter is indicated for measuring absolute and trending regional hemoglobin oxygen saturation of blood (rSO_2) on cerebral sites and trending rSO2 on non-cerebral sites in adults ≥ 40kg.

When used with the O3 Pediatric Sensor, the O3® Regional Oximeter is indicated for measuring absolute and trending regional hemoglobin oxygen saturation of blood (rSO_2) on cerebral sites and trending rSO2 on non-cerebral sites in pediatrics ≥ 5 kg and < 40 kg.

MASIMO CORPORATION
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510(k) Summary

K201432

When used with the O3 Neonatal Sensor, the O3® Regional Oximeter is indicated for measuring only trending regional hemoglobin oxygen saturation of blood (rSO_2) on cerebral sites and trending rSO2 on non-cerebral sites in neonates < 10kg.

The ΔcHb, ΔO2Hb, ΔHHb provided as part of the Masimo O3 are indicated for the monitoring of the relative change of oxygenated hemoglobin (ΔO2Hb), deoxygenated hemoglobin (ΔHHb), and total hemoglobin (ΔcHb) as measured from the Masimo O3 sensor when applied to the cerebral tissue in adults.

3. Technological Characteristics

Principle of Operation

The principle of operation for the O3 Regional Oximeter is based on multi-distance diffusion spectroscopy. Multi-distance diffusion spectroscopy used in the O3 Regional Oximeter relies on the use of differing wavelengths of light that is diffused into a cross-section of tissue consisting of microvasculature (a mixed bed of arterioles, capillaries and venules) and analyzes the light detected after having passed through the tissue from detectors at two different distances from the light source.

Mechanism of Action for Achieving the Intended Effect

The O3 sensor is noninvasively applied to the patient to collect the patient's physiological signals which are processed by the O3 Module. The processed data consists of the rSO2 measurements which are then communicated and displayed on the host/backboard device.

4. Summary of Technological Characteristics of a subject device to the predicate

Similarities and Differences between Subject Device, O3 Regional Oximeter and Predicate Device, O3 Regional Oximeter (K182429)

The subject device, O3 Regional Oximeter, and the predicate device, O3 Regional Oximeter (K182429), have the following key similarities:

- Same intended use for regional oxygen tissue saturation;
- Same principle of operations;
- Same hardware including critical components (e.g., O3 Sensors);
- Same performance specifications for absolute and trending rSO2; and
- Same mechanical and environmental specifications.

The subject device, O3 Regional Oximeter, and the predicate device, O3 Regional Oximeter (K182429), have the following key differences:

- The subject device is indicated for an expanded indication for monitoring tissue oxygen saturation in non-cerebral application sites, whereas the predicate is cleared for monitoring cerebral application sites.

- The subject device is indicated for an expanded indication for monitoring of the relative change of oxygenated hemoglobin (ΔO2Hb), deoxygenated hemoglobin (ΔHHb), and total hemoglobin (ΔcHb) as measured from the Masimo O3 sensor when applied to the cerebral tissue in adults.

The substantial equivalence of the subject device to the predicate device is supported through the use of clinical and non-clinical testing to support the difference does not raise different questions of safety and effectiveness.

5. Performance Data

Biocompatibility Testing

Biocompatibility testing was not required for this submission as there was no change to the materials from the previously cleared O3 sensors (K182429). The cleared sensors were previously evaluated in accordance to ISO 10993 and as a result, the acceptability of the biocompatibility risks for the subject device was determined based on the testing conducted on the predicate sensors.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

Additional Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning testing for this submission was not required as there was no change to the components from the previously cleared O3 Regional Oximeter (K182429).

Software Verification and Validation Testing

As part of this submission, additional Software verification and validation testing was conducted and documented as recommended by FDA's Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005. The software for this device was still considered a "moderate" level of concern. The testing was found to support the substantial equivalence of the subject device.

Wireless and Cybersecurity Testing

Additional Wireless and Cybersecurity testing was not required as part of this submission as there were no changes to the wireless capabilities or communication capabilities of the subject device

from the previously cleared O3 Regional Oximeter (K182429). As a result, the acceptability of the wireless and cybersecurity risks for the subject device were determined based on the testing previously conducted as part of the predicate device clearance.

Human Factors and Usability Testing

Additional Human Factors and Usability was not required as part of this submission as there was no change to the critical user related tasks or need for additional usability risk mitigations for the subject device from the previously cleared predicate device O3 Regional Oximeter (K182429). The human factor and usability consideration are the same as the previously cleared. As a result, the acceptability of the Human factors/ Usability risk for the subject device was determined based upon the testing conducted as part of the predicate device. The cleared predicate O3 Regional Oximeter had previously been tested in accordance with the FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016*.

Non-clinical Performance Testing

Non-clinical performance testing was conducted comparing the performance of the subject device to a FDA cleared regional oximeter for use on non-cerebral sites using a reference phantom. The phantom allowed the simulation of differing levels of oxygenation in order to characterize the performance of both regional oximeters to changes in tissue oxygen levels. The study supported the substantial equivalence of the O3 to FDA cleared regional oximeters in the ability to respond to oxygen level changes.

Clinical Testing

To support the substantial equivalence of the subject device with the expanded indications for use, three clinical studies were conducted.

One clinical study compared the trending ability of the O3 Regional Oximeter to changes in oxygen saturation while the cleared O3 Adult, O3 Pediatric, and O3 Infant/Neonatal Sensors were applied to a non-cerebral application site. The study included 42 adult subjects whose oxygen saturations were decreased in a step-wise controlled desaturation to 70% SpO2. The study used the arterial oxygen saturation (SpO2) as a reference to confirm the actual decrease in the oxygen saturation. The study supported the transferability of the technological characteristics of the O3 Regional Oximeter on non-cerebral application sites.

The second study compared the trending performance of the O3 Regional Oximeter to other cleared regional oximeters using the cleared O3 Adult, O3 Pediatric, and O3 Infant/Neonatal Sensors applied to a non-cerebral application site. The study included 59 adult subjects whose oxygen saturations were decreased in a step-wise controlled desaturation to 70% SpO2. The study supported there are no significant technological characteristic differences in the trending

performance of the O3 Regional Oximeter when applied on non-cerebral application sites using other cleared regional oximeters as a performance reference.

The third study compared the trending performance of the O3 Regional Oximeter to relative changes in oxyhemoglobin, deoxyhemoglobin and total hemoglobin levels (ΔO2Hb, ΔHHb and ΔcHb) to that of a reference predicate with similar features using the cleared O3 Adult sensors applied to the cerebral application site. This study included 22 adult subjects whose hemoglobin concentrations were varied using a hemodilution protocol. The study supported there are no significant technological characteristic differences in trending the performance of O3 Regional Oximeter to that of the reference predicate.

6. Conclusion

The data provided as part of this submission supports the substantial equivalence of the subject device.

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510(k) Summary

K201432