July 17, 2025

Masimo Corporation
Kertana Shankar
Manager, Regulatory
52 Discovery
Irvine, California 92618

Re: K243324
Trade/Device Name: Masimo O3 Regional Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: June 12, 2025
Received: June 12, 2025

Dear Kertana Shankar:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243324

Device Name

Masimo O3 Regional Oximeter

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) 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 sensors in adults, pediatrics, and neonates.

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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52 Discovery
Irvine, CA 92618

510(k) Summary
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Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery, Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	October 21, 2024
Contact:	Kertana Shankar Manager, Regulatory Affairs Masimo Corporation Phone: (949) 390-0140
Trade Name:	Masimo O3 Regional Oximeter
Common Name:	Oximeter, Tissue Saturation
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/MUD
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Expansion of indications for Masimo O3 delta features
Predicate Device:	K214072, Masimo O3 Regional Oximeter

1 Device Description

The Masimo O3 Regional Oximeter is a noninvasive regional oximeter designed to continuously measure and monitor regional hemoglobin oxygen saturation (rSO2) in the tissue under the sensor. The Masimo O3 Regional Oximeter consists of the O3 Module, O3 Sensors (e.g., O3 Adult, O3 Pediatric, O3 Infant/ Neonatal sensors), and a Host/ Backboard Device (e.g., Root).

The Masimo O3 Regional Oximeter System provides the following measurements and calculated features:

- *Regional Oxygenation (rSO2):* Regional tissue oxygenation level in the deep tissue local to the sensor site.
- *Delta Baseline (Δbase):* Calculation of the relative difference in rSO2 with respect to baseline rSO2.
- *Area Under the Limit (AUL index):* Index that quantifies the duration (amount of time) the patient stays below rSO2 low alarm limit and depth (refers to the gap between the patient's rSO2 level and the rSO2 low alarm limit) of patient's stay below the user defined rSO2 low alarm limit (LAL).
- *Delta SpO2 (ΔSpO2):* Calculation of the difference between SpO2 and rSO2. The source of SpO2 is from peripheral SpO2 measurement (using pulse oximeter).
- *Delta HHb (ΔHHb):* Index associated with the relative change in deoxygenated hemoglobin.

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- *Delta O2Hb (ΔO2Hb):* Index associated with the relative change in the oxygenated hemoglobin.
- *Delta cHb (ΔcHb):* Calculation of the sum of the Delta HHb and Delta O2Hb, and is an index, associated with the change in the total (oxygenated and deoxygenated) hemoglobin.

The performance specifications for Masimo O3 Regional Oximeter are provided in Table 1-1 below.

Table 1 Masimo O3 Regional Oximeter Accuracy (A_{RMS}) Specifications		
Cerebral Hemoglobin Oxygen Saturation of Blood (rSO_2)		
rSO_2 (trending) (from 45% to 85% $SavO_2$)	Adult, Pediatric, Neonate	3%
rSO_2 (absolute) (from 45% to 85% $SavO_2$)	Adult	4%
	Pediatric	5%
Non-Cerebral Hemoglobin Oxygen Saturation of Blood (rSO_2)		
rSO_2 (trending) (from 45% to 85% $SavO_2$)	Adult, Pediatric, Neonate	3%
rSO_2 (absolute) (from 60% to 90% $SavO_2$)	Adult	5%

2 Intended Use/ Indications for Use

The indications for use for the Masimo O3 Regional Oximeter are as follows:

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) 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 sensors in adults, pediatrics, and neonates.

3 Technological Characteristics

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There were no changes made to the principles of operation or the mechanism of action of the subject device as part of this submission from the previous clearance under K214072.

Principle of Operation

The Masimo O3 Regional Oximeter system still relies on multi-distance diffusion spectroscopy, which uses differing wavelengths of light diffused into a cross-section of tissue consisting of microvasculature. The light detected after passing through the tissue by detectors at two different distances from the source is analyzed to monitor the deep tissue oxygenation. The delta features (ΔHHb, ΔO2Hb, ΔcHb) calculate the relative changes in the absorption profiles of the different rSO2 components.

Mechanism of Action for Achieving the Intended Effect

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

4 Discussion of Similarities and Differences Between Predicate and Subject Device

Similarities and Differences between Predicate and Subject Device

The subject device, Masimo O3, and the predicate device, Masimo O3 (K214072), have the following key similarities:

- Both devices have the same intended use
- Both devices have the same principle of operation and mechanism of action
- Both devices have the same components (Masimo O3 module, O3 Sensors)

The subject device, Masimo O3, and the predicate device, Masimo O3 (K214072), have the following key differences:

- The subject device is provided with expanded indications for the predicate device cleared delta features (ΔO2Hb, ΔOHHb, ΔcHb).

Between the subject and the predicate device, there are no differences in the intended use and technological characteristics. The difference between the subject device and the predicate device is the expanded indications for the predicate device delta features to include cerebral and non-cerebral tissue in adult, pediatric, and neonatal patients.

To support the substantial equivalence of the delta features for the expanded indications, clinical study data is provided as part of this submission.

See Table 2 for the comparison between the subject and predicate device.

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Table 2 Comparison between Subject and Predicate Device			
Feature	**Masimo O3 Subject Device**	**Masimo O3 Predicate Device (K214072)**	**Comparison to Predicate Device**
Classification	Class II, Oximeter, Tissue Saturation	Class II, Oximeter, Tissue Saturation	Same.
Regulation, Product Code	21 CFR 870.2700/ MUD	21 CFR 870.2700/ MUD	Same.
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 (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) 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	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) 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.	Similar. The subject and predicate devices have the same intended use. The subject device is provided with expanded indications for the delta features (ΔO2Hb, ΔHHb, ΔcHb) to include cerebral and non-cerebral tissue for all populations. Clinical testing is provided to support the substantial equivalence.

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Table 2 Comparison between Subject and Predicate Device			
Feature	**Masimo O3 Subject Device**	**Masimo O3 Predicate Device (K214072)**	**Comparison to Predicate Device**
	relative hemoglobin changes of oxygenated hemoglobin (ΔO2Hb), deoxygenated hemoglobin (ΔHHb), and total hemoglobin (ΔcHb) as measured from the Masimo O3 sensors in adults, pediatrics, and neonates.	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.	
Principles of Operation	Based on multi-distance diffusion spectroscopy. The spectroscopic analysis determines concentrations of hemoglobin in its oxygenated and deoxygenated states monitored at different path lengths to monitor the oxygen saturation in deeper tissue.	Based on multi-distance diffusion spectroscopy. The spectroscopic analysis determines concentrations of hemoglobin in its oxygenated and deoxygenated states monitored at different path lengths to monitor the oxygen saturation in deeper tissue.	Same.
Indicated Population	Adults, Pediatrics, and Neonates	Adults, Pediatrics, and Neonates	Same.
Sensor Application Site	Cerebral (forehead) and non-cerebral (body)	Cerebral (forehead) and non-cerebral (body)	Same.
Supported Parameters (Cerebral)	rSO2 (Adults, Pediatrics, Neonates) ΔO2Hb (Adults, Pediatrics, Neonates) ΔHHb (Adults, Pediatrics, Neonates) ΔcHb (Adults, Pediatrics, Neonates)	rSO2 (Adults, Pediatrics, Neonates) ΔO2Hb (Adults) ΔHHb (Adults) ΔcHb (Adults)	Different. The subject device additionally supports the monitoring of the delta features in pediatrics and neonates. Clinical testing is provided to support the substantial equivalence.

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Table 2 Comparison between Subject and Predicate Device			
Feature	**Masimo O3 Subject Device**	**Masimo O3 Predicate Device (K214072)**	**Comparison to Predicate Device**
Supported Parameters (Non-Cerebral)	rSO2 (Adults, Pediatrics, Neonates) ΔO2Hb (Adults, Pediatrics, Neonates) ΔHHb (Adults, Pediatrics, Neonates) ΔcHb (Adults, Pediatrics, Neonates)	rSO2 (Adults, Pediatrics, Neonates)	Different. The subject device additionally supports the monitoring of delta features on non-cerebral application sites for adults, pediatrics, and neonates. Clinical testing is provided to support substantial equivalence.
Type of Use (sensor)	Single patient use	Single patient use	Same.
Sterility	Supplied non-sterile	Supplied non-sterile	Same.
Performance Specifications (A_{RMS})			
Cerebral rSO2 (Trending, 45% to 85% SavO2)	3%, Adults, Pediatrics, Neonates	3%, Adults, Pediatrics, Neonates	Same.
Cerebral rSO2 (Absolute, 45% to 85% SavO2)	4%, Adults 5%, Pediatrics	4%, Adults 5%, Pediatrics	Same.
Non-cerebral rSO2 (Trending, 45% to 85% SavO2)	3%, Adults, Pediatrics, Neonates	3%, Adults, Pediatrics, Neonates	Same.
Non-cerebral rSO2 (Absolute, 60% to 90% SavO2)	5%, Adults	5%, Adults	Same.
Electrical Specifications			
Power Source	Host device	Host device	Same.

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Table 2 Comparison between Subject and Predicate Device			
Feature	**Masimo O3 Subject Device**	**Masimo O3 Predicate Device (K214072)**	**Comparison to Predicate Device**
Electrical Safety	Conforms to IEC 60601-1	Conforms to IEC 60601-1	Same.
Electromagnetic Compatibility	Conforms to IEC 60601-1-2	Conforms to IEC 60601-1-2	Same.
Environmental Specifications			
Operating Temperature (O3 Module)	32˚F to 104˚F (0˚C to 40˚C)	32˚F to 104˚F (0˚C to 40˚C)	Same.
Operating Temperature (O3 Sensor)	41˚F to 104˚F (5˚C to 40˚C)	41˚F to 104˚F (5˚C to 40˚C)	Same.
Mode of Operation per IEC 60601-1			
Mode of Operation	Continuous	Continuous	Same.

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5 Performance Data

As part of this submission, there were no changes made to the subject device, Masimo O3 Regional Oximeter, from the previous clearance under K214072. Therefore, there were no new bench testing included as part of this submission.

However, clinical study data was provided to support the expanded indications for the delta features.

Performance Bench Testing

As there were no hardware or software changes made to the subject device, Masimo O3 Regional Oximeter, from the previous clearance under K214072, no new performance bench testing was included as part of this submission.

Biocompatibility Testing

As there were no changes made to the patient contacting materials of the subject device, Masimo O3 Regional Oximeter, from the previous clearance under K214072, no new biocompatibility testing was included in this submission.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

As there were no hardware changes made to the subject device, Masimo O3 Regional Oximeter, from the previous clearance under K214072, no new electrical safety, environmental, mechanical, and cleaning testing was included as part of this submission.

Software Verification and Validation Testing

As there were no software changes made to the subject device, Masimo O3 Regional Oximeter, from the previous clearance under K214072, no new software testing was included as part of this submission.

Human Factors and Usability Testing

As there were no changes made to the subject device, Masimo O3 Regional Oximeter, from the previous clearance under K214072, no new human factors or usability testing was included as part of this submission.

Clinical Testing

To support the expanded indications of the Masimo O3 delta features, clinical study data from two studies were included as part of this submission.

The first study data supported the trending ability of the subject device delta features on non-cerebral application sites. This study included data from 25 subjects. The results of the study supported the strong correlation of the non-cerebral trending performance of O3 delta features.

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The second study data supported the trending ability of the subject device delta features when used with the Masimo O3 Pediatric and O3 Neonate sensors. This study included data from 29 subjects. The results of the analysis supported the equivalent performance of the delta features when using Masimo O3 Pediatric and O3 Neonatal sensors.

6 Conclusion

Based on the data provided as part of this submission, the subject device, Masimo O3 Regional Oximeter, was found to be substantially equivalent to the predicate device, K214072.