Masimo Corporation
Kertana Shankar
Regulatory Specialist II
52 Discovery
Irvine, California 92618

Re: K214072
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: March 31, 2022
Received: April 1, 2022

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 (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,

For Purva Pandya
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214072

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) 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 – K214072

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	May 6, 2022
Contact:	Kertana Shankar Regulatory Specialist II Masimo Corporation Phone: (949) 297-7260
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:	Updated indications to include adjunct monitoring of absolute rSO2 in non-cerebral sites
Primary Predicate:	K201432 – Masimo O3 Regional Oximeter System
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 (rSO2) in the tissue 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).

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

- *Regional Oxygenation (rSO_2):* 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 SpO_2 (ΔSpO_2)*: 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 change in deoxygenated hemoglobin.
- *Delta O_2Hb (ΔO_2Hb)*: Index associated with the change in the oxygenated.

- *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 purpose of this submission is to receive clearance for the Masimo O3 Regional Oximeter with updated indications to include adjunct monitoring of absolute rSO2 in non-cerebral sites.

The performance specifications for Masimo O3 Regional Oximeter are provided in **Table 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 proposed intended use/ indications for use for the O3 Regional Oximeter is provided below:

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 sensor when applied to the cerebral tissue in adults.

3 Technological Characteristics

Principle of Operation

There are no changes to the principle of operation from the previous clearance under K201432. The principle of operation for the O3 Regional Oximeter is still based on multi-distance diffusion spectroscopy. Multi-distance diffusion spectroscopy 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

There are no changes to the mechanism of action from the previous clearance under K201432. 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 which mainly consists of the rSO2 values are then communicated and displayed on the host/backboard device.

4 Summary of Technological Characteristics of the subject device compared to the predicate device

Similarities and Differences between Predicate and Subject Device

The subject device, O3 Regional Oximeter, and the predicate device, O3 Regional Oximeter (K201432) have the following key similarities:

- Both devices have the same intended use for regional oxygen tissue saturation
- Both devices are indicated for the same patient population
- Both devices have the same principle of operation and mechanism of action
- Both devices have the same components (such as O3 Module, O3 Sensors)
- Both devices have the same mechanical and environmental specifications
- Both device have the same performance specifications for absolute and trending rSO2 on cerebral sites and trending rSO2 on non-cerebral sites

The subject device, O3 Regional Oximeter, and the predicate device, O3 Regional Oximeter (K201432) have the following key difference:

- The subject device is provided with an updated indication to include adjunct monitoring of absolute regional hemoglobin oxygen saturation of blood (rSO2) in non-cerebral sites in adults.

To support the substantial equivalence, clinical performance testing was performed to support the non-cerebral absolute accuracy. The results of this clinical testing support the added indication does not raise different questions of safety and effectiveness.

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There are no changes to the principles of operation or the mechanism of action from the predicate device and the update to the indications did not modify the intended use of the subject device from the predicate device.

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

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Table 2: Comparison between subject and predicate device			
	Masimo O3 Regional Oximeter	**Masimo O3 Regional Oximeter (K201432)**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate Device**	
General Information			
Indications for Use (IFU)	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	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	Same. The subject device has an updated indications for use to include adjunct monitoring of absolute regional oxygen saturation for non-cerebral sites on adults.

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Table 2: Comparison between subject and predicate device			
	Masimo O3 Regional Oximeter	**Masimo O3 Regional Oximeter (K201432)**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate Device**	
	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.	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.	
Classification Regulation/ Product Code	21 CFR 870.2700/ MUD	21 CFR 870.2700/ MUD	Same
Principle 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
Patient Population	Adult, pediatric, and neonate	Adult, pediatric, and neonate	Same
Anatomical Site	Cerebral (forehead) and non-cerebral (body)	Cerebral (forehead) and non-cerebral (body)	Same
Type of use (sensor)	Single patient use	Single patient use	Same
Sterility	Supplied non-sterile	Supplied non-sterile	Same
Performance (A_{RMS})			
rSO2 cerebral and non-cerebral Trending	3% for SavO2 of 45%-85%	3% for SavO2 of 45%-85%	Same

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Table 2: Comparison between subject and predicate device			
	Masimo O3 Regional Oximeter	**Masimo O3 Regional Oximeter (K201432)**	**Comparison to Predicate Device**
510(k) Number	**Subject Device**	**Primary Predicate Device**	
(Adult, Pediatric, and Neonate)			
rSO2 cerebral Absolute (Adult)	4% for SavO2 of 45%-85%	4% for SavO2 of 45%-85%	Same
rSO2 cerebral Absolute (Pediatric)	5% for SavO2 of 45%-85%	5% for SavO2 of 45%-85%	Same
rSO2 non-cerebral Absolute (Adult)	5% for SavO2 of 60%-90%	--	The subject device is provided with an updated indication to support the adjunct monitoring of absolute rSO2 in non-cerebral sites. The substantial equivalence of the subject device to the predicate device is supported through clinical testing to support the difference does not raise different questions of safety and effectiveness.
Electrical			
Power Source	Host device	Host device	Same
Electrical Safety	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Same
Electromagnetic compatibility	Conformed to IEC 60601-1-2	Conformed to IEC 60601-1-2	Same
Environmental			
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

Biocompatibility Testing

As there are no changes to the patient contacting materials as part of this submission from the previous clearance, no biocompatibility testing was included as part of this submission.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

As there were no changes to the hardware or software as part of this submission from the previous clearance, no additional Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning testing was included with this submission.

Software Verification and Validation Testing

Masimo has established, implemented, and maintains procedures for software design, development, review, verification, and validation of its products in accordance with *FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)*.

As there are no software changes as part of this submission from the previous clearance, no additional software testing was included as part of this submission.

Wireless and Cybersecurity Testing

As the Masimo O3 System uses wired communication for the transfer of parameter data and alarm status, and does not have wireless features at this time, no wireless testing was included as part of this submission.

Human Factors and Usability Testing

There were no changes made to the usability of the O3 Regional Oximeter as part of this submission from the previous clearance (K201432). The O3 Sensor is still applied using the same application method. As there was no significant change to the critical user related steps from the predicate device, the testing provided under the previous clearance K201432 was determined to support the acceptability of the Human factors/ Usability risks. As such, the Human factors/ Usability risk of the subject device was still found to be acceptable

Non-clinical Testing

As there were no hardware, software or non-clinical performance changes made to the subject device when compared to the predicate device (K201432), no additional non-clinical testing was considered necessary to support the substantial equivalence.

Clinical Testing

To support the performance of the subject device in monitoring of absolute rSO2 in non-cerebral sites, clinical testing was provided with this submission. The study was conducted on 25 subjects, whose oxygen saturations were decreased using a controlled desaturation protocol. The Masimo O3 regional

oximeter rSO2 readings on somatic tissue were recorded and compared against the tissue oxygen saturation (SvO2) computed using a combination of arterial and venous blood samples.

The results of the clinical study supported the absolute rSO2 performance on non-cerebral sites.

6 Conclusion

The data provided as part of this submission was found to support the Masimo O3 Regional Oximeter is substantially equivalent to the predicate device.