June 7, 2019

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

Re: K182429
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: April 30, 2019
Received: May 1, 2019

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,

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K182429

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 cerebral region 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 ≥ 40 kg.

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) 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) in neonates < 10 kg.

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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MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7541 FAX: (949) 297-7592
Date:	September 4, 2018
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:	2031172
Reason for Premarket Notification:	New Device – Masimo O3 Neonatal Sensor
Predicate Device:	K160526 – Masimo O3 Regional Oximeter System Reference Predicate: K082327– Somanetics Invos 5100C with Infant/Neonatal Cerebral OxyAlert NIRSensor
Performance Standards	There are no performance standards pursuant to Section 514 of the Food, Drug and Cosmetic Act for the above device.

Device Description

The Masimo Regional Oximetry System (O3 System) monitors regional hemoglobin oxygen saturation of blood (rSO_2) under the sensors. The O3 System includes the O3 Sensors that acquire physiological signals and the O3 Module that processes those signals. The FDA has previously cleared the O3 System in K160526 (with an O3 Adult Sensor) and K162603 (with an O3 Pediatric Sensor). In this submission, Masimo seeks clearance of its O3 System with an O3 Neonatal Sensor.

Similar to the cleared O3 Adult and Pediatric Sensors, the O3 Neonatal Sensor is a single-patient use, adhesive sensor and is supplied non-sterile. The O3 Neonatal Sensor attaches to the patient's forehead. The sensor includes four emitters and two detectors. The emitters radiate multiple wavelengths of near infrared light, while the detectors sense the reflected light. The detector outputs are physiological signals and these signals pass through the other

Section 5. 510(k) Summary

end of the sensor that connects to a patient cable, passing these signals to the O3 Module for processing.

The O3 Module is unchanged from K160526. It includes Masimo technology for processing those signals and outputting regional oximetry (rSO_2) measurements. Specifically, the O3 Module includes Near Infra Red Spectroscopy (NIRS) technology. When O3 module is connected to an O3 Neonatal Sensor, the O3 Monitor continuously and accurately determines the trending measurement of regional blood oxygen saturation in the tissue (rSO_2) in neonates. In turn, the Host/Backboard device displays this measurement. The O3 Module can connect to up to two O3 Sensors, both connected to a patient.

The O3 System does not have an internal battery or an AC power input. The O3 Module, instead, receives power via its connection to a Host/Backboard Device, such as the Root Monitoring System (Root). Root in turn receives power from either AC power or internal rechargeable batteries.

Similar to K160526, the O3 System using an O3 Neonatal Sensor provides the following key measurements:

- *Regional Oxygenation (rSO_2):* Regional tissue oxygenation level in the deep tissue local to the sensor site, including cerebral tissue
- *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 SpO_2 (ΔSpO_2)*: The difference between SpO_2 and rSO_2. The source of SpO_2 is from peripheral SpO_2 measurement (using pulse oximeter).

The O3 System has the following specifications:

O3 System Specifications	
FEATURE	SPECIFICATION
Display	
Display Range	Regional Oxygen Saturation (rSO_2): 0-99%
	Δbase: 0-99% (Δbase is the difference between regional and baseline rSO_2)
Display Resolution for Measurements	rSO_2: 1%
	Δbase: 1%
SO_2 Measurement Accuracy, Neonates < 10 kg	Trending A_{RMS}, 3% for $SavO_2$ of 45%-85%
General	

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O3 System Specifications	
FEATURE	SPECIFICATION
Visual/audible alarm	Host/backboard device (Root per K140188, K151644 and K153225) is IEC60601-1-8 compliant
Storage/recording	Host/backboard device (Root per K140188, K151644 and K153225) trend/data storage
Electrical	
AC Power or Battery, Rechargeable	Host/backboard device (Root per K140188, K151644 and K153225) provides power to O3 System
Interface	
O3 Module Connection	MOC-9 interface with host/backboard device (Root per K140188, K151644 and K153225)
Mechanical	
O3 Module: Dimensions/Weight	5x1.8x0.6 inch/ 7 oz
O3 Neonatal Sensor: Dimensions/Weight	2.6x1.1x0.1 inch/0.18 oz.
Environmental	
O3 Module	
• Operating Temperature	0°C to +40°C, ambient humidity
• Storage Temperature	-40°C to +70°C, ambient humidity
• Operating/ Storage Humidity	10% to 95%, non-condensing
• Altitude	Up to 12,000 feet (3700 meters)
O3 Adult Sensor, O3 Pediatric, and O3 Neonatal Sensor	
• Operating Temperature	+5°C to +40°C
• Storage Temperature	-40°C to +60°C
• Humidity	15% to 90% relative humidity

* $SavO_2 = 0.3\ SaO_2 + 0.7\ SjvO_2$

Intended 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 cerebral region 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.

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 cerebral region 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.

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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) 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) in neonates < 10 kg.

Technological Characteristics

Principle of Operation (same as in K160526)

> The O3 System's operating principle is based on multi-distance diffuse reflectance spectroscopy. The O3 System use light to examine a cross-section tissue microvasculature (a mixed bed of arterioles, capillaries and venules) and analyzes the light returned after having passed through the tissues. The spectroscopic analysis determines concentrations of hemoglobin in its oxygenated and deoxygenated states.

Mechanism of Action for Achieving the Intended Effect (same as in K160526)

> The O3 Sensor is noninvasively applied to the patient on one end. The other end of the O3 Sensor connects to the O3 Module. In turn, the O3 Module connects to a Host/Backboard device. The O3 Sensor collects patient physiological signals which are processed by the O3 Module. The processed signals which resulted in rSO_2 measurements are displayed on the Host/Backboard device.

Non-clinical Testing

Masimo performed the following tests, as applicable, for the qualification of the subject devices, O3 System under K160526 in accordance with the requirements of the design control regulations and established quality assurance processes to demonstrate substantial equivalence with the predicate device:

- Electrical safety testing per IEC-60601-1
- EMC testing per IEC-60601-1-2
- Alarm testing per IEC-60601-1-8
- Biocompatibility testing per ISO-10993
- Software verification per FDA Software Guidance
- Mechanical and environmental testing

Masimo performed the following tests, as applicable, for the qualification of the subject devices, O3 Neonatal sensor in accordance with the requirements of the design control regulations in and established quality assurance processes to demonstrate substantial equivalence with the predicate device cleared in K160526

- Usability testing per FDA Human Factors and Usability Guidance

The results demonstrate that all requirements and performance specifications were satisfied, and that the subject device is substantially equivalent to the predicate device.

Clinical Testing

Masimo performed a clinical study to determine the O3 Neonatal Sensor's Trending A_{RMS}. Previously, Masimo performed a clinical study on the O3 Adult Sensor to establish its trending accuracy with respect to blood testing.

In this submission, Masimo collected relative rSO_2 data for both the O3 Adult Sensor and O3 Neonatal Sensor on the same subject to calculate the O3 Neonatal Sensor's Trending A_{RMS} relative to the O3 Adult Sensor. Masimo then calculated the Trending A_{RMS} for the O3 Neonatal Sensor relative to blood from a combination of the O3 Adult Sensor's Trending A_{RMS} relative to blood testing and O3 Neonatal Sensor's Trending A_{RMS} relative to the O3 Adult Sensor.

Masimo also conducted a study to test the absolute accuracy of the subject sensor on 11 hospitalized patients weighing less than 10 kg with invasive $SavO_2$ blood draws of 46 % to 82 %. The study showed a favorable trend of rSO2 with $SavO_2$ with an accuracy of less than 6 %. Note that absolute accuracy is not a claim that is being pursued in this submission. These data are merely being reported as convenience samples.

Conclusion

The clinical evaluation, non-clinical testing including safety testing, as included in this 510(k) submission, demonstrate that the subject device, O3 Neonatal Sensor, is substantially equivalent to its predicate with respect to safety and effectiveness.