DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2017

Masimo Corporation
Marguerite Thomlinson
Sr. Director, Regulatory Affairs
52 Discovery
Irvine, California 92618

Re: K162603
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 25, 2017
Received: April 26, 2017

Dear Marguerite Thomlinson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -S
2017.05.26 11:06:05 -04'00'

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162603

Device Name

Masimo O3 Regional Oximeter System

Indications for Use *(Describe)*

The noninvasive Masimo O3 Regional Oximeter System and accessories are intended for use as an adjunct monitor of absolute and trended regional hemoglobin oxygen saturation of blood (rSO2) in the cerebral region under the sensors. The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥ 40 kg and on pediatrics > 5 kg and < 40 kg in healthcare environments.

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) 297-7683 FAX: (949) 297-7592
Date:	May 10, 2017
Contact:	Marguerite Thomlinson Senior Director, Regulatory Affairs
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 Pediatric Sensor
Predicate Device:	K160526 – Masimo O3 Regional Oximeter System K082327– Invos 5100C with Pediatric SomaSensor
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

Device Description

The Masimo Regional Oximetry System (O3 System) includes the O3 Sensors and the O3 Module. The O3 System measures hemoglobin under the sensor, allowing clinicians to continuously and accurately determine the absolute and trend measurements of regional blood oxygenation saturation in the tissue (rSO_2). The O3 Sensors includes optical components that collect physiological signals. The O3 Module includes Masimo technology for processing those signals which resulted in regional oximetry (rSO2) measurements. In turn, these measurements are displayed on the Host/Backboard device.

The O3 Sensor is a single-patient use adhesive sensor and is supplied non-sterile. The O3 Sensor, comprising of an emitter and two detectors, is applied to the patient's forehead at one end. The other end of the sensor is connected to a patient cable which in turn is connected to

Section 5. 510(k) Summary

the O3 Module. Up to two O3 Sensors can be connected to each O3 Module and both sensors can be connected to a patient.

The O3 Module includes Near InfraRed Spectroscopy (NIRS) technology. The O3 Sensor uses multiple wavelengths in the range of near infrared wavelengths to measure light absorption in the tissue. The O3 Sensors and O3 Module make up the O3 System for the monitoring of absolute regional hemoglobin oxygen saturation of blood (rSO2) under the sensors. The O3 System does not have its own power. The O3 Module is powered by connecting to a Host/Backboard Device such as the Root Monitoring System (Root). Root in turn is powered by either AC power or internal rechargeable batteries.

The O3 System provides the following key measurements:

- *Regional Oxygenation (rSO2):* Regional tissue oxygenation level in the deep tissue local to the sensor site, including cerebral tissue
- *Delta Baseline (Δbase):* 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)*: The difference between SpO2 and rSO2. The source of SpO2 is from peripheral SpO2 measurement (using pulse oximeter).

See the table below for the O3 System specifications.

O3 System Specifications	
FEATURE	SPECIFICATION
Display	
Display Range	Regional Oxygen Saturation (rSO2): 0-99%
	Δbase: 0-99% (Δbase is the difference between regional and baseline rSO2)
Display Resolution for Measurements	rSO2: 1%
	Δbase: 1%
rSO2 Measurement Accuracy, Adults ≥ 40kg	Absolute A_{RMS}, 4% for SavO2 of 45%-85%
	Trending A_{RMS}, 3% for SavO2 of 45%-85%
SO2 Measurement Accuracy, Pediatrics ≥ 5 kg and < 40 kg	Absolute A_{RMS}, 5% for SavO2 of 45%-85%
	Trending A_{RMS}, 3% for SavO2 of 45%-85%
General	
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

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O3 System Specifications	
FEATURE	SPECIFICATION
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 Large Sensor: Dimensions/Weight	2.9x1.5x0.1 inch/0.20 oz.
O3 Pediatric 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 Large Sensor and O3 Pediatric Sensor	
• Operating Temperature	+5°C to +40°C
• Storage Temperature	-40°C to +60°C
• Humidity	15% to 90% relative humidity

Intended Use

The O3 System, consisting of the O3 Sensors and O3 Module, is intended for noninvasive monitoring of absolute regional oxygen saturation. The computed saturation values are displayed on a host/backboard monitor such as the Masimo Root System (K140188, K151644 and K153225). The O3 System is intended to be used in healthcare environments.

Indications For Use

The noninvasive Masimo O3 Regional Oximeter System and accessories are intended for use as an adjunct monitor of absolute and trended regional hemoglobin oxygen saturation of blood (rSO2) in the cerebral region under the sensors. The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥ 40 kg and on pediatrics ≥ 5 kg and < 40 kg in healthcare environments.

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Irvine, CA 92618

Section 5. 510(k) Summary

Technological Characteristics

Principle of Operation

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

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 rSO2 measurements are displayed on the Host/Backboard device.

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52 Discovery
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Section 5. 510(k) Summary

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

		Table 12.5	
FEATURE	**Masimo O3 Regional Oximeter System (with O3 Pediatric Sensor)**	**Masimo O3 Regional Oximeter System (with O3 Large Sensor)**	**Somanetics Invos System (with Pediatric SomaSensor)**
510(k) Number	**Pending**	**Predicate: K160526**	**Predicate: K082327**
General Information			
Indications for Use (IFU)	The noninvasive Masimo O3 Regional Oximeter System and accessories are intended for use as an adjunct monitor of absolute and trended regional hemoglobin oxygen saturation of blood (rSO2) in the cerebral region under the sensors. The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥ 40 kg and on pediatrics ≥ 5 kg and < 40 kg in healthcare environments.	The noninvasive Masimo O3 Regional Oximeter System and accessories are intended for use as an adjunct monitor of absolute and trended regional hemoglobin oxygen saturation of blood (rSO2) in the cerebral region under the sensors. The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥ 40 kg in healthcare environments.	The noninvasive INVOS 5100C is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor. It is intended for use in individuals greater than 2.5 kg risk for reduced-flow or no-flow ischemic states. It is also intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor in any individual. The clinical value of trend data has not been demonstrated in disease states. The INVOS System should not be used as the sole basis for diagnosis or therapy.
Classification Regulation/ Product Code	Same as K160526 and K082327	21 CFR 870.2700/ MUD	21 CFR 870.2700/ MUD
Principle of Operation	Same as K160526	The O3 System operating principle is based on multi-distance diffuse reflectance spectroscopy. The device uses 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 tissue. The spectroscopic analysis determines concentrations of hemoglobin in its oxygenated and deoxygenated states.	The Invos 5100C is a 2 wavelength, diffuse reflectance spectroscopy system employing near infrared light to estimate the percentage of hemoglobin saturated with oxygen in tissue underneath the sensor. An adhesive sensor containing a light source and 2 photodiodes is applied to the skin over the tissue of interest and the returning light is analyzed for oxyhemoglobin and deoxyhemoglobin light absorption. Absorption signals from the photodiode closer to the light

Section 5. 510(k) Summary

		Table 12.5	
FEATURE	**Masimo O3 Regional Oximeter System (with O3 Pediatric Sensor)**	**Masimo O3 Regional Oximeter System (with O3 Large Sensor)**	**Somanetics Invos System (with Pediatric SomaSensor)**
510(k) Number	**Pending**	**Predicate: K160526**	**Predicate: K082327**
			source are subtracted from those from the farther photodiode where the returning photons penetrate more deeply in the tissue.
Patient Population	Adults ≥ 40 kg Pediatrics ≥ 5 kg and < 40 kg	Adults ≥ 40 kg	Pediatrics < 40 kg
Measurement Site	Same as K160526 and K082327	Cerebral region, forehead	Cerebral region, forehead
Type of Use	Same as K160526 and K082327	Single patient use	Single patient use
Sterility	Same as K160526 and K082327	Supplied non-sterile	Supplied non-sterile
Accuracy (A_{RMS}) *			
Absolute Accuracy	5% for SavO2 of 45%-85%	4% for SavO2 of 45%-85%	N/A
Trending Accuracy	3% for SavO2 of 45%-85%	3% for SavO2 of 45%-85%	1.6% SaO2 of 74%-100% (per K082327 SaO2 range is for adults)
Dimensions			
System Compatibility			
Monitoring System	Same as K160526	Root Monitoring System with O3 Module	Invos System
Biocompatibility			
Materials	Same as K160526 and K082327	Biocompatible, ISO-10993 compliant	Biocompatible, ISO-10993 compliant
Mechanical			
Overall Dimension	2.6x1.1x0.1 inch	2.9x1.5x0.1 inch	3.0x1.5x.1 inch
Weight	0.18 oz	0.20 oz	0.2 oz
Environmental			
Operating Temperature	Same as K160526	5°C to 40°C	16°C to 32°C
Storage Temperature	Same as K160526	-40°C to 60°C	-20°C to 45°C
Humidity	Same as K160526	15% to 90% non-condensing	20% to 80%, non-condensing

* A_{RMS} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- A_{RMS} of the reference measurements in a controlled study.

Section 5. 510(k) Summary

Non-clinical Testing

The following tests, as applicable, were performed for the qualification of the subject devices, O3 System, 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
- Optical safety testing per IEC-62471
- Biocompatibility testing per ISO-10993
- Usability testing per FDA Human Factors and Usability Draft Guidance
- Software verification per FDA Software Guidance
- Mechanical and environmental testing

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

In the study for Absolute A_{RMS}, rSO2 measurements were collected using the O3 System, including the O3 Module (K160526) and O3 Pediatric Sensor, on 33 male and female pediatric patients with ages ranging from less than one year to 12 years. Blood draws (arterial and jugular blood) were taken for each subject before and after his/her medical procedure. The rSO2 measurements were analyzed against blood draw measurements and the Absolute A_{RMS} were calculated in the same manner as in K160526.

As the O3 Large Sensor trending accuracy was established with blood reference via K160526, the O3 Large Sensor was used as a reference in the comparative trending study with the O3 Pediatric Sensor. The rSO2 data was collected for both O3 Large Sensor and O3 Pediatric Sensor. The relative rSO2 value between the O3 Large Sensor and O3 Pediatric Sensor was then calculated. The Trending A_{RMS} for the O3 Pediatric Sensor was derived by taking the relative error between the O3 Large Sensor and O3 Pediatric Sensor into account.

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Irvine, CA 92618

Section 5. 510(k) Summary

Conclusion

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