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

June 9, 2016

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

Re: K160526
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 10, 2016
Received: May 11, 2016

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 yours,

Shawn W. Forrest -S
2016.06.09 22:39:04 -04'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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)*
K160526

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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 09, 2016
Contact:	Marguerite Thomlinson Senior Director, Regulatory Affairs
Trade Name:	Masimo O3 Regional Oximeter System
Common Name:	Oximeter, Tissue Saturation
Regulation Number/ Name/ Product Class	21 CFR 870.2700, Class II/MUD
Establishment Registration Number:	2031172
Reason for Premarket Notification:	New Device
Predicate Devices:	K133879 – Fore-Sight Elite Absolute Tissue Oximeter
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 connected to the O3 Module. Up to two O3 Sensors can be connected to each O3 Module and both sensors can be connected to a patient.

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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.

TABLE 5a O3 System Specifications	
FEATURE	SPECIFICATION
Display	
Display Range	Regional Oxygen Saturation (rSO2): 0-99%
	ΔSpO2: 0-99%
	Δbase:0-99%
Display Resolution for Measurements	1%
Measurement Accuracy	rSO2 (trending): ≤ 3% (RMS)
	rSO2 (absolute): ≤ 4% (RMS)
	Difference between Regional and Baseline rSO2 (Δbase): 1%
General	
Visual/audible alarm	Host/Backboard Device (Root) is IEC60601-1-8 compliant per K140188
Storage/recording	Root has trend/data storage per K140188
Electrical	
AC Power	Host/Backboard Device (Root) provides AC power per K140188
Battery, Rechargeable	Host/Backboard Device (Root) provides internal battery power per K140188
Interface	
O3 Module Connection	MOC-9 interface with Host/Backboard device (Root, per

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TABLE 5a O3 System Specifications	
FEATURE	SPECIFICATION
	K140188)
Mechanical	
O3 Module: Dimensions/Weight	145.2x1.8x0.6 inch (including cable length)/7 oz. 5x1.8x0.6inch (without cable).
O3 Sensor: Dimensions/Weight	44x1.5x0.64 inch (including max cable length)/1.3 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 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 Sensor and O3 Module are intended for noninvasive monitoring of regional oxygen saturation. The computed saturation values are displayed on a Host/Backboard monitor such as the Masimo Root Monitoring System. 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 in healthcare environments.

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

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Section 5. 510(k) Summary

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 signal which resulted in rSO2 measurements are displayed on the Host/Backboard device.

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

The subject device, O3 System, and the predicate device, Casmed Fore-Sight Elite Oximeter (K133879), have the following key similarities:

- Both devices include near infrared technology (using LEDs) for rSO2 measurements;
- Both devices have the same intended use;
- Both devices have the same measurement site;
- Both devices are intended for the same subject populations of individuals weighing $\geq$ 40 kg;
- Both devices include single-use adhesive sensors.

The subject device, O3 System, and the predicate device, Casmed Fore-Sight Elite Oximeter (K133879), have the following key difference:

In the subject device, the regional measurement technology is in the O3 Module. Whereas, in the predicate device, the regional measurement technology is distributed in the module and the host device. This is simply a choice of where the technology hardware is placed in the housings.

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Table 5b Substantial Equivalence Table- Comparison Between Predicate and Subject Device			
Feature	**Fore-Sight Elite Absolute Tissue Oximeter**	**O3 Regional Oximeter System (O3 Sensor and O3 Module)**	**Differences and Similarities between Subject & Predicate Device**
510(k) Number	**K133879 (Predicate)**	**Pending (Subject Device)**	
General Information			
Parameter monitored	Regional hemoglobin oxygen saturation of blood in the microvasculature of brain tissue	Regional hemoglobin oxygen saturation of blood in the microvasculature of brain tissue	Same
Patient population	Adults and transitional adolescents ≥ 40 kg.	Adults ≥ 40 kg	Same
Sensor Type	Disposable adhesive sensor with biocompatible patient contact materials	Disposable adhesive sensor with biocompatible patient contact materials	Same
Performance accuracy	Cerebral: 45% to 95% ±3.05% to 1 standard deviation with large sensors.	Cerebral: 45% to 85% ±3% to 1 standard deviation with large sensors (trending) Cerebral: 45% to 85% ±4% to 1 standard deviation with large sensors (absolute)	Similar The proposed device is seeking approval for a subset of the range already cleared in the predicate device.
Device	Oximeter, Tissue Saturation	Oximeter, Tissue Saturation	Same
Regulation description	Oximeter	Oximeter	Same
Regulation medical specialty	Cardiovascular	Cardiovascular	Same
Review panel	Cardiovascular	Cardiovascular	Same
Product code	MUD	MUD	Same
Regulation number	870.2700	870.2700	Same
Device class	2	2	Same
Indications for Use			

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Table 5b Substantial Equivalence Table- Comparison Between Predicate and Subject Device			
Feature	**Fore-Sight Elite Absolute Tissue Oximeter**	**O3 Regional Oximeter System (O3 Sensor and O3 Module)**	**Differences and Similarities between Subject & Predicate Device**
510(k) Number	**K133879 (Predicate)**	**Pending (Subject Device)**	
	The noninvasive Fore-Sight Elite Absolute Tissue Oximeter is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced flow or no-flow ischemic states and is indicated as follows: When used with large sensors, the Fore-Sight Elite Oximeter is indicated for use on adults and transitional adolescents ≥ 40 kg.	The noninvasive Masimo O3 Regional Oximeter System is 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, in individuals at risk for reduced flow or no-flow ischemic states and is indicated as follows: The Masimo O3 Regional Oximeter System and accessories are indicated for use on adults ≥ 40 kg in healthcare environments.	Same Predicate device specifies absolute accuracy; subject device specifies absolute and trended accuracy, which is a property of absolute accuracy.
Principle of operation			
	The Fore-Sight Elite's operating principle is based on multi-distance diffuse reflectance spectroscopy. The monitor 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.	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.	Same
Device display			
Display type	Touchscreen	Touchscreen	Same
Display	LCD	LCD	Same
Trend display	Yes	Yes	Same
Measurement			
Method (Technology)	Near Infrared Spectroscopy (NIRS)	Near Infrared Spectroscopy (NIRS)	Same

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Table 5b Substantial Equivalence Table- Comparison Between Predicate and Subject Device			
Feature	**Fore-Sight Elite Absolute Tissue Oximeter**	**O3 Regional Oximeter System (O3 Sensor and O3 Module)**	**Differences and Similarities between Subject & Predicate Device**
510(k) Number	**K133879 (Predicate)**	**Pending (Subject Device)**	
Sensor placement site	Right and Left Forehead	Right and Left Forehead	Same
Anatomical measurement site	Brain (via forehead) non-invasive	Brain (via forehead) non-invasive	Same
Mode of operation	Continuous monitoring	Continuous monitoring	Same
Sensor Information			
Technology	Noninvasive LED-based technology (incoherent light)	Noninvasive LED-based technology (incoherent light)	Same
Materials			
Biocompatibility	Patient contact materials are biocompatible per ISO 10993-1	Patient contact materials are biocompatible per ISO 10993-1	Same
Power			
External AC power	100 to 240 VAC, 50/60 Hz	100-240 VAC, 47-63 Hz	Same
Internal battery	Rechargeable internal battery	Rechargeable internal battery	Same
Visual Comparison			
System components	Monitor, Module and Sensor	Host/Backboard (Monitor) Device, Module and Sensor	Same

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

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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

The clinical study was done on healthy adult male and female subjects with light to dark skin pigmentation. The trending and absolute rSO2 accuracies were determined by testing in the range of 45% to 85% SavO2 against 30% arterial and 70% jugular venous blood oxygen saturations, measured by a laboratory CO-Oximeter. The study confirms that the O3 System measurements meet the requirements.

Conclusion

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