DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 22, 2015

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

Re: K150314
Trade/Device Name: Masimo MightySat Rx Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 16, 2015
Received: September 18, 2015

Dear Ms. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

Section 4. Indications for Use Statement

Indications for Use

510(k) Number: K150314

Device Name: Masimo MightySat Rx Fingertip Pulse Oximeter

Indications for Use:

The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR). The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for use with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and mobile environments.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5. 510(k) Summary

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	October 21, 2015
Contact:	Marguerite Thomlinson Senior Director, Regulatory Affairs
Trade Name:	Masimo MightySat Rx Fingertip Pulse Oximeter
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/DQA
Establishment Registration Number:	2031172
Reason for Premarket Notification:	New Device
Predicate Device:	K081285 – Nonin Medical, Inc. Onyx II Model 9560 K142394 – Masimo Root Monitoring System (Radius-7)
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

Device Description

The subject device, MightySat Rx, is a fingertip pulse oximeter that includes Masimo SET technology for the measurement of functional oxygen arterial hemoglobin (SpO2) and pulse rate in adults and pediatrics. The device is a spot check pulse oximeter and does not include alarms. The device has the combined function of a pulse oximeter monitor and a reusable sensor. It includes an OLED color display, enclosed by plastic housing and powered by two alkaline AAA batteries. The MightySat Rx also includes optional Bluetooth wireless technology for the wireless transfer of patient data to mobiles devices, such as a smartphone.

The mobile device functions as a secondary display and it is not required for the intended use of pulse oximetry measurements. After measurements are made by the subject device, the data can be transferred to the mobile device via Bluetooth for the display and/or storage of the data.

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The MightySat Rx noninvasively measures and displays the following Masimo SET parameters:

- *Functional Oxygen Saturation of Arterial Hemoglobin (SpO2):* The amount of oxyhemoglobin expressed a percentage of the hemoglobin
- *Pulse Rate (PR):* Measured in beats per minute (BPM) is based on the optical detection of peripheral flow pulse
- *Perfusion Index (PI):* The ratio of the pulsatile blood flow to the non-pulsatile in peripheral tissue. PI thus represents a non-invasive measurement of peripheral perfusion that can be obtained from the pulse oximeter.
- *Optional Pleth Variablility Index (PVI):* Measure of dynamic changes in perfusion index that occur during the respiratory cycle. The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI is displayed as a percentage (0-100%).

The MightySat Rx base device includes SpO2, PR and PI parameters. It can also include the optional PVI and/or Bluetooth wireless features.

See the table below for the MightySat Rx specifications.

FEATURE	**SPECIFICATION**
Display	
Display Type	OLED color display
Display Range	Oxygen Saturation (SpO2): 0-100%
	Pulse Rate (PR): 25-240 beats per minute (bpm)
	Perfusion Index (PI): 0.02-20%
	Pleth Variability Index (PVI): 0-100%
Display Waveform	Plethysmograph
	Signal IQ
Display Resolution	SpO2: 1%
	PR: 1 bpm
Measurement Accuracy in Accordance with ISO 80601-2-61	
SpO2, No Motion	70 – 100%, 2%, Arms, adults/pediatrics
SpO2, Motion	70 – 100%, 3% Arms, adults/pediatrics
SpO2, Low Perfusion	70 – 100%, 2%, Arms, adults/pediatrics
Pulse Rate, No Motion	25 – 240 bpm, 3 bpm Arms, adults/pediatrics
Pulse Rate, Motion	25 – 240 bpm, 5 bpm Arms, adults/pediatrics
Pulse Rate, Low Perfusion	25 – 240 bpm, 3 bpm Arms, adults/pediatrics
Power	
Internal battery	Two Alkaline AAA batteries
Interface	
Wireless	Bluetooth LE
Mechanical	
Enclosure Material	Plastic, Cycoloy
Dimensions/Weight	2.9” x 1.6 ” x 1.2” (7.4 cm x 4.1 cm x 3.0 cm)
Weight	0.16 lbs (73 g)
Environmental	
Operating Temperature	5°C to +40°C, ambient humidity

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FEATURE	SPECIFICATION
Storage Temperature	-40°C to +70°C, ambient humidity
Operating/ Storage Humidity	10% to 95%, non-condensing
Altitude	Up to 5,486 meters (18,000 feet)
Mode of Operation	
Mode of Operation	Spot check

Intended Use/Indications for Use

The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for use with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, and mobile environments.

Technological Characteristics

Principle of Operation

Pulse oximetry is governed by the following principles:

- Oxyhemoglobin (oxygentated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
- The amount of arterial blood in tissue changes with your pulse (photoplethysymography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

Mechanism of Action for Achieving the Intended Effect

MightySat Rx automatically turns on when the device is opened . The device is then positioned on the patient's finger. Once the device is applied on the finger, it collects, processes physiological signals, and then displays Masimo SET measurements on the device's display screen. The MightySat Rx automatically turns off after removing the device from the finger.

Summary of Technological Characteristics of Subject Device Compared to Predicate Device

Similarities and Differences between Primary Predicate Device, Nonin Onyx II 9560 Pulse Oximeter (K081285) and Subject Device, MightySat Rx

The subject device, MightySat Rx, and the primary predicate device, Nonin Onyx II 9560 Pulse Oximeter (K081285), have the following key similarities:

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- Both devices have the same intended use as a spot checking fingertip pulse oximeter with SpO2 and PR measurements;
- Both devices have the same principle of operations of pulse oximetry;
- Both devices do not have alarms;
- Both devices have the same measurement site;
- Both devices include wireless Bluetooth feature for transferring patient information from the device to a mobile device, such as a smartphone; and
- Both devices are internally powered by two AAA batteries

The subject device, MightySat Rx, and the primary predicate device, Nonin Onyx II 9560 Pulse Oximeter (K081285), have the following key differences:

- The subject device is indicated for use under motion conditions, whereas the predicate is not;
- The subject device includes a color OLED display and the predicate includes an LED display; and
- The subject device includes PVI calculation and the predicate does not have this feature.

Similarities and Differences between Predicate Device, Masimo Radius-7 (K142394) and Subject Device, MightySat Rx

The subject device, MightySat Rx, and the predicate device, Masimo Radius-7 (K142394), have the following key similarities:

- Both devices include the Masimo SET technology;
- Both devices display SpO2, PR, PI, PVI, and pleth and Signal IQ waveforms;
- Both devices have the same principle of operation for pulse oximetry;
- Both devices include wireless Bluetooth feature; and
- Both devices have an OLED color display and touchpad interface.

The subject device, MightySat Rx, and the predicate device, Masimo Radius-7 (K142394), have the following key differences:

- The subject device is a spot check device without alarms and the predicate is a continuous monitoring device with alarms;
- The subject device combines the functionality of an instrument and a sensor into a single device, whereas the predicate is an instrument that needs to connect with a sensor; and
- The subject device does not have acoustic respiratory rate measurement (RRa), whereas the predicate includes the RRa measurement.

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Non-clinical Testing

The subject device was subjected bench testing. The following non-clinical testing, as applicable, was performed in accordance with Masimo design control requirements and quality system to demonstrate substantial equivalence of the subject device with its predicates:

- Electrical safety testing per IEC60601-1
- EMC testing per IEC60601-1-2
- Pulse oximetry testing per ISO 80601-2-61
- Biocompatibility testing per ISO-10993-1, ISO-10993-5 and ISO-10993-10
- Usability testing per FDA Human Factors and Usability Draft Guidance
- Software verification per FDA Software Guidance
- Mechanical and environmental testing including:
    - shock and vibration,
    - shipping drop test,
    - mechanical durability and
    - storage/transport and operational temperatures

Clinical Testing

The MightySat Rx was subjected to clinical testing. The functional oxygen saturation (SpO2) measurement has been validated in accordance with ISO 80601-2-61. The clinical testing was completed on a total of 14 healthy adult male and female volunteers (with at least a total of 356 blood samples) with light to dark skin pigmentations in the range of 70% to 100% against a laboratory CO-Oximeter. The SpO2 accuracy results include:

- 1.66% which meets the accuracy requirement of less than or equal to 2% under no motion condition and
- 2.30% which meets the accuracy requirement of less than or equal to 3% under motion conditions.

The accuracy specification is reported as accuracy root mean square (Arms).

Conclusion

The non-clinical and clinical testing provided in this 510(k) submission demonstrates that the subject device, MightySat Rx Fingertip Pulse Oximeter, as safe and as effective, and substantially equivalent to its predicates.