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

Re: K181956
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, BZQ
Dated: December 20, 2018
Received: December 26, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181956

Device Name

Masimo MightySat Rx Fingertip Pulse Oximeter

Indications for Use *(Describe)*

The Masimo MightySat Rx Fingertip Pulse Oximeter is intended for hospitals, hospital-type facilities, home environments, and transport.

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) for adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of respiration rate (RRp) for adult patients.

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) 297-7000 FAX: (949) 297-7199
Submitter:	Sindura Penubarthi
Date:	December 20, 2018
Contact:	Sindura Penubarthi
Trade Name:	Masimo MightySat Rx Fingertip Pulse Oximeter
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/DQA
Additional Product Code:	BZQ
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Additional or Expanded Indications
Primary Predicate Device:	K141518 – Nellcor Bedside Respiratory Patient Monitoring System
Secondary Predicate Device:	K150314 – Masimo MightySat Rx Fingertip Pulse Oximeter
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

Device Description

The subject device, MightySat Rx, was previously cleared under K150314 as a fingertip pulse oximeter that includes Masimo SET technology for the measurement of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), calculation of Perfusion Index (Pi) and optional Pleth Variability Index (PVi) in adults and pediatrics. The current submission concerns the MightySat Rx's measurement of respiration rate through photoplethysmogram analysis (designated as RRp).

Like the secondary predicate (K150314), 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.

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The MightySat Rx also includes optional Bluetooth wireless technology for the wireless transfer of patient data to mobile devices, such as a smartphone.

Intended Use/Indications for Use

The Masimo MightySat Rx Fingertip Pulse Oximeter is intended for hospitals, hospital-type facilities, home environments, and transport.

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) for adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of respiration rate (RRp) for adult patients.

The Indications for Use statement for the MightySat Rx is similar to the primary predicate (K141518). Both the subject and predicate device have the same intended use for vital sign monitoring, by transmitting and detecting light through tissue in the finger.

Device Specifications

The MightySat Rx specifications are as follows:

FEATURE	SPECIFICATION
Display	
Display Type	OLED color display
Display Range	Oxygen Saturation (SpO_2): 0-100%
	Pulse Rate (PR): 25-240 beats per minute (BPM)
	Perfusion Index (Pi): 0.02-20%
	Pleth Variability Index (PVi): 0-100%
	Respiration rate (RRp): : 4-70 respirations per minute (RPM)
Display Waveform	Photoplethysmogram
	Signal IQ
Display Resolution	SpO_2: 1%
	PR: 1 BPM
	RRp: 1 RPM
Measurement Accuracy in Accordance with ISO 80601-2-61	
SpO_2, No Motion	70 – 100%, 2%, A_{RMS}, adults/pediatrics
SpO_2, Motion	70 – 100%, 3% A_{RMS}, adults/pediatrics
SpO_2, Low Perfusion	70 – 100%, 2%, A_{RMS}, adults/pediatrics
Pulse Rate, No Motion	25 – 240 BPM, 3 BPM A_{RMS}, adults/pediatrics
Pulse Rate, Motion	25 – 240 BPM, 5 BPM A_{RMS}, adults/pediatrics
Pulse Rate, Low Perfusion	25 – 240 BPM, 3 BPM A_{RMS}, adults/pediatrics
RRp	4 – 70 RPM, 3 RPM A_{RMS}, 1 RPM Mean Error, adults
Power	

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FEATURE	SPECIFICATION
Internal battery	Alkaline "AAA" batteries
Interface	
Wireless	Bluetooth LE
Mechanical	
Enclosure Material	Plastic
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
Storage Temperature	-40°C to +70°C, ambient humidity
Operating/ Storage Humidity	10% to 95%, non-condensing
Atmospheric Pressure	540 mBar to 1060 mBar
Mode of Operation	
Mode of Operation	Spot Check

Technological Characteristics

Principle of Operations

The MightySat Rx's principle of operation for Masimo SET technology is similar to the primary predicate (K141518). Specifically, the Masimo SET technology uses a two-wavelength sensor to measure the indicated parameters based on light absorption principles of oxygenated blood and deoxygenated blood which generates a photoplethysmogram. Respiration rate (RRp) measures the respiration rate by analyzing cyclic variations in the photoplethysmogram due to respiration.

Mechanism of Action for Achieving the Intended Effect

The MightySat Rx's mechanism of action is similar to the primary predicate (K141518) and the same as the secondary predicate (K150314). 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 to the finger, it collects and 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 the Primary Predicate

Similarities and Differences between Predicate and Subject Device, MightySat Rx

The subject device, MightySat Rx, and the Primary Predicate (K141518), have the following key similarities:

- Both devices have the same intended use as vital sign monitors;
- Both devices have the same technological characteristics with respect to pulse oximetry with SpO_2 and PR measurements;

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- Both devices can display photoplethysmogram and Signal IQ waveforms;
- The subject device can calculate a respiration rate (RRp);
- Both devices have the same measurement site;

The subject device, MightySat Rx, and the Primary Predicate (K141518), have the following key difference:

- The subject device is intended for home environments;
- The subject device's intended use has been updated to indicate for transport, whereas the secondary predicate (K150314) used the term mobile environments;
- Device includes optional wireless Bluetooth feature for transferring patient information from the device to a mobile device (e.g. smartphone), the same as the secondary predicate (K150314);
- Both devices are internally powered, except subject device uses "AAA" alkaline batteries the same as the secondary predicate (K150314); and
- Subject device provides Perfusion Index (Pi) and Pleth Variability Index (PVi) the same as the secondary predicate (K150314).

The sole technological difference between the subject device and the secondary predicate (K150314) is the addition of the RRp measurement. The technology change is a software change which utilizes the same hardware as the secondary predicate. The difference does not raise different questions of safety and effectiveness. This is supported by the primary predicate, the Nellcor™ Bedside Respiratory Patient Monitoring System (K141518). The primary predicate and subject device are both part of the same DQA and BZQ product codes. Both the subject device and predicate device utilize similar principles of operation which measures respiration rate from the photoplethysmogram obtained by transmitting and detecting of light though a finger. Both devices rely on the technological principle of respiration-induced variations in the photoplethysmogram. Specifically, both devices rely on the general principle that respiration modulates the frequency, amplitude, and intensity of the photoplethysmograph as described in Karlen, W., Raman, S., Ansermino, J.M., Dumont, G.A.: *Multiparameter respiratory rate estimation from the photoplethysmogram*. IEEE Transactions on Biomedical Engineering 60(7), 1946–1953 (2013). The subject and primary predicate measure respiration rate from these modulations of the photoplethysmogram; however, they may differ in the method in which the signal is processed. Both signal processing methods, have similar performance.

Performance Data

The following performance data were provided in support of substantial equivalence determination.

Biocompatibility Testing

There was no change in the patient contacting material as part of this submission. The MightySat Rx includes patient contacting materials as the sensor is positioned on the patient's finger. It is substantially the same as the cleared secondary predicate (K150314) with respect to biocompatibility. Therefore, the testing performed and submitted with K150314 with respect to ISO 10993-1, ISO 10993-5 and ISO 10993-10 supports the substantial biocompatibility

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equivalence evaluation.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning
There was no change to the hardware as part of this submission. The subject device is substantially the same as previously cleared under K150314. Therefore, the testing performed and submitted with K150314 with respect to the IEC 60601-1 standard for basic safety and essential performance, the IEC 60601-2-1 standard for EMC, environmental, mechanical, and cleaning applies to the subject device. Because the subject device includes the added environments of home and transport, additional testing was performed regarding EMC immunity for the home and transport environment in accordance with the FDA's guidance, *Design Considerations for Devices Intended for Home Use* dated November 24, 2014 and IEC 60601-1-2:2014.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005. The software for this device was considered as a "moderate" level of concern, because a failure or latent flaw in the software could directly result in minor to moderate injury to the patient similar to the predicate.

Wireless Testing
There is no difference between the wireless capabilities of the subject device and the predicate device. The subject device relies on the wireless testing demonstrating the connectivity (i.e. Bluetooth pairing) between MightySat Rx and mobile devices, such as smartphones, submitted in secondary predicate device, cleared MightySat Rx (K150314). That testing was done in accordance with FDA Guidance, *Radio-Frequency Wireless Technology in Medical Devices*, dated August 14, 2013.

Human Factors Usability Testing
The use-related changes from the predicate device to the subject device are: (1) the addition of the RRp measurement to the MightySat Rx graphical interface, and (2) the expanded intended use to cover home use. Because the addition of the RRp measurement does not impact the mechanism of action of the MightySat Rx and only makes a minor change to the layout to accommodate the additional parameter, the human factors and usability risk were found to be acceptable based upon the previous testing conducted as part of the predicate device, cleared MightySat Rx (K150314).

To address the use by home users, the human factors and usability testing was conducted using non-clinicians to support the acceptability of the human factors and usability risks associated with home users. To further minimize risks associated with use in the home environment, the subject device was subjected to additional testing for home use per IEC 60601-1-11:2010 and in accordance with FDA Guidance, *Guidance for Industry and Food and Drug Administration Staff*

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- *Design Considerations for Devices Intended for Home Use*, dated November 24, 2014.

Non-clinical Testing
In K150314, Masimo included non-clinical testing of the predicate device in accordance with ISO 80601-2-61 for SpO_2, pulse rate and perfusion index. Masimo performed additional, non-clinical testing in accordance with Masimo design control requirements and quality system with respect to RRp to ensure that the specifications of the subject device were met.

Clinical Testing
In K150314, Masimo included clinical testing of the predicate device for the SpO_2 measurement. Because there was no change to the SpO_2 measurement function of the device as part of this submission, the clinical study for SpO_2 was not repeated.

For this submission to add the RRp, Masimo performed two additional clinical tests of the MightySat Rx to validate the measurement performance of respiration rate (RRp) measurement. The first study was a prospective analysis to validate the accuracy of the RRp measurement on 28 healthy volunteers. The second study was a retrospective analysis of data from 59 hospitalized subjects to validate the performance of the RRp measurement on subjects with different clinical conditions. Masimo's clinical tests measured RRp against manual, clinician-scored capnograms (obtained from a $Capnostream_{20}$, Oridion, Needham, MA, K060065). The results from the prospective clinical study and retrospective clinical study demonstrated substantial equivalence of the MightySat Rx to the primary predicate.

Conclusion

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