February 27, 2020

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

Re: K193242
Trade/Device Name: Masimo Rad-97 Pulse CO-Oximeter and Accessories, Masimo Radical-7 Pulse CO-Oximeter and Accessories, Masimo Radius-7 Pulse CO-Oximeter and Accessories
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, BZQ, CCK, DQA, DPZ, DXN, FLL
Dated: January 24, 2020
Received: January 27, 2020

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,

for Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193242

Device Name
Masimo Rad-97 Pulse CO-Oximeter and Accessories

Indications for Use *(Describe)*
Masimo Rad-97 Pulse CO-Oximeter and Accessories:

The Masimo Rad-97 and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station). In addition, the Masimo Rad-97 and Accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Rad-97 and Accessories for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) to multi-parameter devices for the display on those devices.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Rad-97 and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The optional Nomoline Capnography product family is intended to be connected to other medical backboard devices for monitoring of breath rate and CO2. The Nomoline Capnography product family is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The environment is the operating suite, intensive care unit and patient room. The intended patient population is adult, pediatric and infant patients.

The optional non-invasive blood pressure (NiBP) module is indicated for the noninvasive measurement of arterial blood pressure. The NiBP module is designed to measure blood pressure for patient population described in the following Table:

Patient Population Approximate Age Range
Newborn (neonate) Birth to 1 month of age
Infant 1 month to 2 years of age

Child 2 to 12 years of age
Adolescent 12-21 years of age
Adult 21 years of age and older

Devices with Masimo technology are only to be used with Masimo sensors and cables.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from photoplethysmogram (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K193242

Device Name
Masimo Radical-7 Pulse CO-Oximeter and Accessories

Indications for Use *(Describe)*
Masimo Radical-7 Pulse CO-Oximeter and Accessories

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Radical-7 and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from photoplethysmogram (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

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)

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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)*
K193242

Device Name
Masimo Radius-7 Pulse CO-Oximeter and Accessories

Indications for Use *(Describe)*
Masimo Radius-7 Pulse CO-Oximeter and Accessories:

The Radius-7 Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Radius and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from Pleth (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

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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Section 5. 510(k) Summary

For the Rad-97

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	November 21st 2019
Contact:	Sindura Penubarthi Regulatory Affairs Manager Masimo Corporation Phone: (949) 297-7541
Trade Name:	Masimo Rad-97 Pulse CO-Oximeter and Accessories
Common Name:	Patient Monitor
Classification Regulation/ Product Code:	21 CFR 870.2300, Class II/MWI
Additional Product Code:	21 CFR 868.2375, Class II/BZQ 21 CFR 862.3200, Class II/JKS 21 CFR 868.1400, Class II/CCK 21 CFR 870.2700, Class II/DQA 21 CFR 870.2710, Class II/DPZ 21 CFR 870.1130, Class II/DXN 21 CFR 880.2910, Class II/FLL
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Addition of RRp Feature
Predicate Device:	K183697 – Masimo Rad-97 and Accessories
Reference predicate:	K181956 – Masimo MightySat Rx Fingertip Pulse Oximeter
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

For the Radical-7:

Trade Name:	Masimo Radical-7 Pulse CO-Oximeter and Accessories
Common Name:	Oximeter

Section 5. 510(k) Summary

Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/DQA
Additional Product Code:	21 CFR 868.2375, Class II/BZQ 21 CFR 862.3200, Class II/JKS 21 CFR 870.2710, Class II/DPZ
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Addition of RRp Feature
Predicate Device:	K171121 – Masimo Radical-7 Pulse CO-Oximeter and Accessories
Reference predicate:	K181956 – Masimo MightySat Rx Fingertip Pulse Oximeter
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

For the Radius-7:

Trade Name:	Masimo Radius-7 Pulse CO-Oximeter and Accessories
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/DQA
Additional Product Code:	21 CFR 868.2375, Class II/BZQ 21 CFR 862.3200, Class II/JKS 21 CFR 870.2710, Class II/DPZ
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Addition of RRp Feature
Predicate Device:	K171121 – Masimo Radius-7 Pulse CO-Oximeter and Accessories
Reference predicate:	K181956 – Masimo MightySat Rx Fingertip Pulse Oximeter
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

Section 5. 510(k) Summary

5.1. Device Description

The subject of the submission is to add Respiration Rate from photoplethysmogram (designated as RRp) feature to the previously cleared Masimo Pulse Oximetry devices. The RRp feature is a feature that was previously cleared as part of MightySat fingertip pulse oximeter under K181956. RRp feature determines the patient's respiration rate by analyzing cyclic variations in photoplethysmogram (pleth) to establish respiration measurement. The devices in which the RRp feature is being added as part of this submission are the previously cleared Masimo Rad-97 Pulse CO-Oximeter and Accessories, Masimo Radical-7 Pulse CO-Oximeter and Accessories, and Masimo Radius-7 Pulse CO-Oximeter. These devices are described below.

Rad-97 Pulse CO-Oximeter:

Masimo Rad-97 System and Accessories (Rad-97), is a portable monitor that features a touchscreen that provides a display and control user interface for monitored parameters. The Rad-97 product family can be operated on AC power or internal rechargeable battery.

The Rad-97 comprises of technologies that enable the device to provide noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), Perfusion Index (Pi), Pleth Variability Index (PVi), carboxyhemoglobin (SpCO), methemoglobin (SpMet), total hemoglobin (SpHb), oxygen content (SpOC), acoustic respiration rate (RRa), and/or capnography parameters or noninvasive blood pressure (NIBP) parameters which were all previously cleared under K183697.

The subject of this submission is the addition of the RRp feature to the Rad-97. The technological characteristics of the RRp feature is the same as that of previously cleared reference predicate MightySat (K181956). The RRp feature utilizes the same pleth waveform data from the same sensors used in SpO2 monitoring to detect the signals used for determining a respiration rate.

There are no changes to hardware and environmental specifications for Rad-97 and the hardware specifications remain the same as compared to the predicate. The performance specifications have been updated to include those of the RRp feature. See performance specifications for the Rad-97 listed in Table1 below.

Table 1 - Rad-97	
Feature	**Specification**
Accuracy (A_{RMS})*	**Masimo Rainbow SET/ Masimo SET Parameters**
SpO_2, no motion	70-100%, 1.5%, adults/pediatrics/infants 70-100%, 3%, neonates
SpO_2, motion	70-100%, 1.5% adults/pediatrics/infants 70-100%, 3%, neonates
SpO_2, low perfusion	70-100%, 2%, adults/pediatrics/infants/neonates
Pulse rate, no motion	25-240 bpm, 3 bpm, adults/pediatrics/infants/neonates
Pulse rate, motion	25-240 bpm, 5 bpm, adults/pediatrics/infants/neonates
Pulse rate, low perfusion	25-240 bpm, 3 bpm, adults/pediatrics/infants/neonates
RRa	4-70 rpm, 1 rpm, adults/pediatrics

Section 5. 510(k) Summary

	4-120 rpm, 1 rpm, infants/neonates
RRp	4-70 rpm, 3 rpm A_{RMS}, 1 rpm Mean Error , adults/pediatrics
SpCO	1-40%, 3%, adults/pediatrics/infants
SpMet	1-15%, 1%, adults/pediatrics/infants/neonates
SpHb Limits of Agreement (LOA) over a range of 8-17 g/dL	-1.83 to 1.57 g/dL adults/pediatrics
Optional	**Nomoline Capnography**
CO2	Single dry gasses at 22± 5°C and 1013 ± hPa: 0-15 volume % ±0.2 volume% +2% or reading All conditions: 0.3 kPa + 4% of reading
Respiration rate	0-150 bpm ± 1 bpm
Optional	**Non-invasive blood pressure**
NiBP	0-300 mmHg, ±3 mmHg

*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.*

Radical-7 Pulse CO-Oximeter:

Masimo Radical-7 and Accessories, is a pulse co-oximeter that features a touchscreen that provides a display and control user interface for monitored parameters. It can be used either as a handheld or standalone monitor. Radical-7 can interface with a multi-parameter patient monitor and send data in order to display on the monitor.

The Radical-7 comprises of technologies that enable the Radical-7 to provide noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), Perfusion Index (Pi), Pleth Variability Index (PVi), carboxyhemoglobin (SpCO), methemoglobin (SpMet), total hemoglobin (SpHb), and acoustic respiration rate (RRa) parameters which were all previously cleared under K171121.

The subject of this submission is the addition of RRp feature to the Radical-7. The technological characteristics of the RRp feature is the same as that of previously cleared reference predicate MightySat (K181956). The RRp feature utilizes the same pleth waveform data from the same sensors used in SpO2 monitoring to detect the signals used for determining a respiration rate.

There are no changes to hardware and environmental specifications for Radical-7 and the hardware specifications remain the same as compared to the predicate. The performance specifications have been updated to include those of the RRp feature. See performance specifications for the Radical-7 is listed in Table 2 below.

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Table 2 - Radical-7	
Feature	**Specification**
Accuracy (A_{RMS})*	**Masimo Rainbow SET/ Masimo SET Parameters**
SpO_2, no motion	70-100%, 2%, adults/pediatrics/infants 70-100%, 3%, neonates
SpO_2, motion	70-100%, 3% adults/pediatrics/infants/neonates
SpO_2, low perfusion	70-100%, 2%, adults/pediatrics/infants/neonates
Pulse rate, no motion	25-240 bpm, 3 bpm, adults/pediatrics/infants/neonates
Pulse rate, motion	25-240 bpm, 5 bpm, adults/pediatrics/infants/neonates
Pulse rate, low perfusion	25-240 bpm, 3 bpm, adults/pediatrics/infants/neonates
RRa	4-70 rpm, 1 rpm, adults/pediatrics
	4-120 rpm, 1 rpm, infants/neonates
RRp	4-70 rpm, 3 rpm A_{RMS}, 1 rpm Mean Error , adults/pediatrics
SpCO	1-40%, 3%, adults/pediatrics/infants
SpMet	1-15%, 1%, adults/pediatrics/infants/neonates
SpHb	8-17 g/dL, 1 g/dL adults/pediatric

**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.*

Radius-7 Pulse CO-Oximeter:

Masimo Radius-7 and Accessories, is a wearable Pulse CO-Oximeter. Radius-7 can interface with a multi-parameter patient monitor and send data in order to display on the monitor via Bluetooth or WiFi.

The Radius-7 comprises of technologies that enable the Radius-7 to provide noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), Perfusion Index (Pi), Pleth Variability Index (PVi), carboxyhemoglobin (SpCO), methemoglobin (SpMet), total hemoglobin (SpHb), and acoustic respiration rate (RRa) parameters which were all previously cleared under K171121.

The subject of this submission is the addition of RRp feature to the Radius-7. The technological characteristics of the RRp feature is the same as that of previously cleared reference predicate MightySat (K181956). The RRp feature utilizes the same pleth waveform data from the same sensors used in SpO2 monitoring to detect the signals used for determining a respiration rate.

There are no changes to hardware and environmental specifications for Radius-7 and the hardware specifications remain the same as compared to the predicate. The performance specifications have been updated to include those of the RRp feature. See performance specifications for the Radius-7 listed in Table 3 below.

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Table 3 - Radius-7	
Feature	**Specification**
Accuracy (A_{RMS})*	**Masimo Rainbow SET/ Masimo SET Parameters**
SpO_2, no motion	70-100%, 2%, adults/pediatrics/infants 70-100%, 3%, neonates
SpO_2, motion	70-100%, 3% adults/pediatrics/infants/ neonates
SpO_2, low perfusion	70-100%, 2%, adults/pediatrics/infants/neonates
Pulse rate, no motion	25-240 bpm, 3 bpm, adults/pediatrics/infants/neonates
Pulse rate, motion	25-240 bpm, 5 bpm, adults/pediatrics/infants/neonates
Pulse rate, low perfusion	25-240 bpm, 3 bpm, adults/pediatrics/infants/neonates
RRa	4-70 rpm, 1 rpm, adults/pediatrics 4-120 rpm, 1 rpm, infants/neonates
RRp	4-70 rpm, 3 rpm A_{RMS}, 1 rpm Mean Error , adults/pediatrics
SpCO	1-40%, 3%, adults/pediatrics/infants
SpMet	1-15%, 1%, adults/pediatrics/infants/neonates
SpHb	8-17 g/dL, 1 g/dL, adults/pediatric

**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.*

5.2. Intended Use/ Indications for Use

Masimo Rad-97 Pulse CO-Oximeter and Accessories:

The Masimo Rad-97 and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station). In addition, the Masimo Rad-97 and Accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Rad-97 and Accessories for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) to multi-parameter devices for the display on those devices.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Rad-97 and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

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The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The optional Nomoline Capnography product family is intended to be connected to other medical backboard devices for monitoring of breath rate and CO2. The Nomoline Capnography product family is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The environment is the operating suite, intensive care unit and patient room. The intended patient population is adult, pediatric and infant patients.

The optional non-invasive blood pressure (NiBP) module is indicated for the noninvasive measurement of arterial blood pressure. The NiBP module is designed to measure blood pressure for patient population described in the following Table:

Patient Population	Approximate Age Range
Newborn (neonate)	Birth to 1 month of age
Infant	1 month to 2 years of age
Child	2 to 12 years of age
Adolescent	12-21 years of age
Adult	21 years of age and older

Devices with Masimo technology are only to be used with Masimo sensors and cables.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from photoplethysmogram (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

Masimo Radical-7 Pulse CO-Oximeter and Accessories

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

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The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Radical-7 and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from photoplethysmogram (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

Masimo Radius-7 Pulse CO-Oximeter and Accessories:

The Radius-7 Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The Masimo Radius and Accessories are not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities.

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The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of total hemoglobin concentration (SpHb) of adult and pediatric patients during no motion conditions in hospitals and hospital-type facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

The Radius-7 and Accessories are indicated for the continuous non-invasive monitoring of Respiratory Rate from Pleth (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.

5.3. Technological Characteristics

Principle of Operation

The subject of this submission is the addition of the optional RRp feature. The RRp feature is based upon the operating principle that a subject's respiration rate creates a cyclic variation in photoplethysmogram (i.e. pleth or PPG) that can be used to establish a respiration rate measurement. The Pleth is derived from the absorption of red/infra-red wavelengths of light used in SpO2 and Pulse rate monitoring.

Mechanism of Action for Achieving the Intended Effect

The RRp feature is provided through the same mechanism of action as SpO2 monitoring. The RRp respiration rate is provided by first applying a SpO2 sensor to the application site (e.g. finger). The SpO2 sensor then detects the physiological variations which result in the variation in the absorption of the wavelength that are signals used to display the pleth. The detected physiological signals are then processed to identify the cyclic variations associated with the expression of the respiration rate upon the pleth. The RRp feature further processes those cyclic variations to estimate the respiration rate which then displayed to the clinician. Alarm thresholds can then be set for RRp to support the continuous monitoring of the respiration rate by a clinician. Clinicians can discontinue the use of the RRp feature simply by removing the SpO2 sensor.

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5.4. Summary of Technological Characteristics of Subject Device Compared to Predicate Device

The Subject Devices (Rad-97, Radical-7, and Radius-7) and the Predicate devices have the following key similarities:

- Both devices have the same intended use as a patient monitoring device;
- Both devices have the same hardware and environmental specifications;
- Both devices have the same input/output interfaces;

The Subject Devices (Rad-97, Radical-7, and Radius-7) and the Predicate devices have the following key differences:

- Subject device includes the addition of the Respiration Rate from pleth (RRp) feature

5.5. Performance Data

Biocompatibility Testing:

No additional biocompatibility testing was included, since there are no new patient contacting parts as part of this submission. The RRp feature utilizes the same already cleared sensors used for SpO2 monitoring. As a result, there was no change to the biocompatibility between the previously cleared patient contacting parts.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

No additional testing was included, since there were no electrical, mechanical, environmental modifications made to the predicate devices since the latest clearance to support the addition of RRp feature. As a result, additional testing for Electrical Safety, Environmental, Mechanical and cleaning were not deemed necessary to demonstrate substantial equivalence to the predicate devices.

Additional EMC testing has been provided to support the compliance to IEC 60601-1-2 4th edition for Rad-97, Radical-7 and Radius-7.

Software Verification and Validation Testing

Software verification and validation testing was conducted and the documentation is 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. The testing was found to support

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the substantial equivalence of the subject device.

Cybersecurity Testing

In accordance with the FDA guidance for Cybersecurity, the subject devices (Rad-97, Radical-7 and Radius-7) were considered tier 2 devices. Cybersecurity considerations were made in accordance with FDA *Guidance for Industry and Food and Drug Administration Staff- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,* dated October 2, 2014 and draft guidance dated October 18, 2018. To support the subject devices do not raise any new questions of safety and effectiveness a risk-based assessment and testing in accordance with referenced FDA guidance documents were conducted. The addition of RRp feature to the subject devices, do not introduce any new safety concerns from the previously cleared devices Rad-97 (K183697), Radical-7 (K171121), and Radius-7 (K171121).

Wireless Testing

Addition of RRp feature on the subject devices (Rad-97, Radical-7, and Radius-7) do not modify the wireless communications/capabilities (quality of service, coexistence, security and electromagnetic compatibility of the devices) from the cleared predicate devices. As a result, the previous wireless testing still supports the substantial equivalence to the predicate devices. The addition of RRp parameter to the subject devices, did not introduce any new safety concerns related to the wireless capabilities from the previously cleared devices Rad-97 (K183697), Radical-7 (K171121), and Radius-7 (K171121).

Human Factors Usability Testing

The previous human factors and usability testing conducted on the predicate devices was found to be acceptable based upon similarities in the user interface between the subject and the predicate devices even with the additional of RRp feature. There was no change to the prospective work flow from the cleared predicate devices. Previous testing already took account the human factors and usability of the parameter display when provided with a similar number of parameters. Additionally, there is no change to the intended environment where the devices were to be used with the RRp feature. To support the acceptability of the human factors and usability risk, as part of the predicate device clearances the acceptability of the human factors and usability risks were established in accordance with the FDA Guidance, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design,* dated February 3, 2016. As part of the evaluation, the user related tasks were categorized based upon risk to establish critical user related tasks. Knowledge Task Assessment and Simulate Use testing was conducted to determine the completion of the critical user tasks and the assessment did not result in any unacceptable human factors and usability risks. Based on the previous evaluation, addition of RRp feature on the subject devices do not raise any new questions of safety and effectiveness. The previous testing conducted on the predicates as part of their clearances was found to

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support the substantial equivalence of the subject devices.

Non-clinical Performance Bench Testing

To support the substantial equivalence of the RRp feature to that of the predicate, non-clinical bench simulation testing was conducted to support the RRp feature is substantially equivalent. The bench testing supported the substantial equivalence of the performance of the RRp feature to be provided on the subject devices to the RRp feature provided on the reference device, MightySat Rx (K181956). The testing was found to support the RRp feature does not raise new questions of substantial equivalence.

Clinical Testing

In order to support the substantial equivalence of the subject devices with the addition of RRp to the previously cleared devices, Masimo performed clinical studies (two retrospective and one prospective) and provided the data as part of this submission. The results were found to be equivalent to RRp feature previously FDA cleared on the MightySat (K181956).

As part of the prospective clinical study, Masimo obtained multiple respiration rate measurements from healthy adult subjects using a representative Masimo device (Rad-97) which included the RRp feature and compared the RRp values against measurements from a FDA cleared capnography device as a gold-reference method (Oridion Capnostream$_{20}$, K060065). The comparison of RRp against the reference supported an Arms of 2.1 RPM.

As part of the retrospective clinical validation study using adult data, the raw photoplethysmogram (pleth) captured using Masimo SET sensors, and the capnography waveforms, from a FDA cleared capnography device as a gold-reference method (Oridion Capnostream$_{20}$, K060065), collected on hospitalized adults was used to compare the calculated RRp values against that of the respiration rates from the reference method. The comparison of RRp against that of the reference capnography an Arms of 2.5 RPM.

As part of the retrospective clinical validation study using pediatric data, the raw photoplethysmogram (pleth), captured using Masimo SET sensors, and the capnography waveforms, from a FDA cleared capnography device as a gold-reference method (Oridion Capnostream$_{20}$, K060065), collected on hospitalized pediatrics was used to compare the calculated RRp values against that of the respiration rates from the reference method. The comparison of RRp against that of the reference capnography an Arms of 2.0 RPM.

The clinical data provided as part of this submission supports the performance specification of the RRp feature as compared to a gold-reference capnography for the measurement of the respiration rate meets an Arms of $\leq$ 3.0RPM and mean error of 1, the same as the previously FDA cleared MightySat (K181956). See summary of analysis in the Table 4 below.

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Table 4 Summary of clinical data analysis				
Study	**Number of Data Points**	**Mean Error (RPM)**	**Standard Deviation (RPM)**	**ARMS (RPM)**
Clinical (Prospective) – Healthy Adults	7751	0.2	2.1	2.1
Clinical (Retrospective) – Hospitalized Adults	119174	0.5	2.5	2.5
Clinical (Retrospective) – Hospitalized Pediatrics	35390	0	2.0	2.0

5.6. Conclusion

The data provided as part of this submission supports the subject devices are substantially equivalent to the predicate devices.