March 6, 2023

Masimo Corporation
Kertana Shankar
Regulatory Specialist II
52 Discovery
Irvine, California 92618

Re: K212161
Trade/Device Name: Radical-7 Pulse CO-Oximeter and Accessories, Rad-97 and Accessories
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, BZQ, JKS, CCK, DPZ, DXN, FLL
Dated: May 27, 2022
Received: May 31, 2022

Dear Kertana Shankar:

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,

James J. Lee -S

James J. Lee, PhD
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthsia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212161

Device Name
Rad-97 and Accessories

Indications for Use *(Describe)*
The Rad-97 and Accessories is a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospital, hospital type facilities, mobile and home environments.

The Rad-97 and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station).

The Rad-97 and Accessories are indicated for the non-invasive spot-checking and continuous 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.

The Rad-97 and Accessories are indicated for the non-invasive continuous monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions.

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

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

The Rad-97 and Accessories are indicated for the continuous monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions.

In addition, the Rad-97 and Accessories are indicated to provide the non-invasive spot-checking and continuous monitoring data obtained from the 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 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 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 Rad-97 and accessories are indicated for the non-invasive continuous monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) of adults during no motion conditions.

PVi may be used as a noninvasive dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.

The Rad-97 and Accessories are indicated for the non-invasive continuous monitoring of respiratory rate from Pleth (RRp) for adult and pediatric patients during no motion conditions.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212161

Device Name
Radical-7 and Accessories

Indications for Use *(Describe)*

The Radical-7 and Accessories are indicated for the non-invasive spot-checking and continuous 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 non-invasive continuous monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The 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 non-invasive continuous 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 non-invasive continuous 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 non-invasive continuous 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 non-invasive continuous 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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MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

510(k) Summary
K212161

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	February 22, 2023
Contact:	Kertana Shankar Senior Regulatory Specialist Masimo Corporation Phone: (949) 297-7260
Trade Name:	Rad-97 and Accessories
Common Name:	Patient Monitor
Classification Regulation/ Product Code:	21 CFR 870.2300, Class II/MWI
Additional Product Code:	21 CFR 870.2700, Class II/DQA 21 CFR 868.2375, Class II/BZQ 21 CFR 862.3200, Class II/JKS 21 CFR 868.1400, Class II/CCK 21 CFR 870.2710, Class II/DPZ 21 CFR 870.1130, Class II/DXN 21 CFR 880.2910, Class II/FLL
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Update indications for use to include spot-checking
Predicate Device:	K193626 – Rad-97 and Accessories
Reference Predicate Device	K201770 – Rad-G and Accessories
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

Trade Name:	Radical-7 and Accessories
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/DQA

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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:	3011353843
Reason for Premarket Notification:	Update indications for use to include spot-checking
Predicate Device:	K193242 – Radical-7 Pulse CO-Oximeter and Accessories
Reference Predicate Device	K201770 – Rad-G and Accessories
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

1. Device Description

This premarket notification [510(k)] is for the authorization to market the previously cleared Rad-97 (K193626) and Radical-7 (K193242) with an additional indication for spot-checking.

The cleared versions of the subject devices already support both continuous monitoring and spot-checking use through the activation and deactivation of alarms. This submission updates the indications to reflect both uses of the subject devices.

Rad-97

The Rad-97 is a patient monitor capable of providing multiple parameters. The Rad-97 product family provides the integrated ability of 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), Pleth Respiration Rate (RRp), capnography parameters, and noninvasive blood pressure (NiBP) parameters.

The subject device is the same as the predicate cleared under K193626 with exception of the updated indications for spot-checking.

The specifications for Rad-97 are as follows:

Feature	**Rad-97 Specification**
Performance	**Accuracy (A_{RMS})***
SpO2, no motion, 70-100%	1.5%, adults/ pediatrics/ infants/ neonates**
SpO2, motion, 70-100%	1.5% Arms, adults/ infants/ pediatrics/ neonates **
SpO2, low perfusion, 70-100%	2%, adults/ pediatrics/ infants/ neonates

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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
SpCO, 1-40%	3%, adults/ pediatrics / infants
SpMet, 1-15%	1%, adults/ pediatrics/ infants/ neonates
SpHb, 8-17 g/dL	1g/dL adults/ pediatrics
RRa, 4-70 rpm, 4-120 rpm	1 rpm, adults/ pediatrics 1 rpm, infants/ neonates
RRp, 4-70 rpm	3 rpm ARMS, 1 rpm Mean Error, adults/ pediatrics
CO2	Single dry gasses at 22±5°C and 1013±40 hPa: 0-15 volume %: ±(0.2 volume% +2% or reading)
	All conditions: ±(0.3 kPa + 4% of reading)
NiBP	0-300 mmHg, ISO 81060-2

**ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- ARMS of the reference measurements in a controlled study.*
*** Applicable with RD SET Disposable sensors*

Radical-7

The Radical-7 is a noninvasive monitor that measures arterial oxygen saturation (SpO_2), pulse rate (PR), perfusion index (Pi), Pleth Variability Index (PVi), totalhemoglobin (SpHb), carboxyhemoglobin (SpCO), total oxygen content (SpOC), methemoglobin (SpMet), acoustic respiration rate (RRa), and Pleth Respiration Rate (RRp).

The subject device is the same as the predicate cleared under K193242 with exception of the updated indications for spot-checking.

The Specifications for Radical-7 are as follows:

Feature	**Radical-7 Specification**
Performance	**Accuracy (A_{RMS})***
SpO_2, no motion, 70-100%	2%, adults/ pediatrics/ infants; 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 4-120 rpm	1 rpm, adults/ pediatrics 1 rpm, infants/ neonates
RRp, 4-70rpm	3 rpm ARMS, 1 rpm Mean Error, adults/ pediatrics
SpCO, 1-40%	3%, adults/ pediatrics/ infants

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Feature	Radical-7 Specification
SpMet, 1-15%	1%, adults/ pediatrics/ infants/ neonates
SpHb, 8-17 g/dL	1 g/dL, adults/ pediatrics

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

2. Intended Use/ Indications for Use

Rad-97

The Rad-97 and Accessories is a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospital, hospital type facilities, mobile and home environments.

The Rad-97 and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station).

The Rad-97 and Accessories are indicated for the non-invasive spot-checking and continuous 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.

The Rad-97 and Accessories are indicated for the non-invasive continuous monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions.

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

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

The Rad-97 and Accessories are indicated for the continuous monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions.

In addition, the Rad-97 and Accessories are indicated to provide the non-invasive spot-checking and continuous monitoring data obtained from the 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 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 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

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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 Rad-97 and accessories are indicated for the non-invasive continuous monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) of adults during no motion conditions.

PVi may be used as a noninvasive dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.

The Rad-97 and Accessories are indicated for the non-invasive continuous monitoring of respiratory rate from Pleth (RRp) for adult and pediatric patients during no motion conditions.

Radical-7

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

3. Technological Characteristics

Principle of Operation

As part of this submission, there were no changes to the principles of operation for the Rad-97 and Radical-7 from their respective predicates, Rad-97 (K193626) and Radical-7 (K193242).

The devices use the same previously cleared Masimo SET pulse oximetry technology, which relies on the following principle:

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

Mechanism of Action for Achieving the Intended Effect

The mechanism of action for the subject devices is the same as that of their predicates (K193626 and K193242). The optical-based parameters still rely on the application of an optical sensor to a capillary application site to detect physiological signals, which are processed to estimate the parameters (e.g., SpO2 and Pulse Rate). Both devices already support the ability to activate and deactivate parameter alarms through the user interface.

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Feature	Rad-97 Subject Device	Rad-97, Predicate device	Comparison to the Predicate Device
510(k) Number	**K212161**	**K193626**	
General Information			
Primary Classification Regulation/ Product code	21 CFR 878.2300, Class II/MWI	21 CFR 878.2300, Class II/MWI	Same
Additional Classification Regulation/ Product Code(s)	21 CFR 870.2700, Class II/DQA 21 CFR 862.3200, Class II/JKS 21 CFR 868.1400, Class II/CCK 21 CFR 868.2375, Class II/BZQ 21 CFR 870.2710, Class II/DPZ 21 CFR 870.1130, Class II/DXN 21 CFR 880.2910, Class II/FLL	21 CFR 870.2700, Class II/DQA 21 CFR 862.3200, Class II/JKS 21 CFR 868.1400, Class II/CCK 21 CFR 868.2375, Class II/BZQ 21 CFR 870.2710, Class II/DPZ 21 CFR 870.1130, Class II/DXN 21 CFR 880.2910, Class II/FLL	Same
Indications for Use	The Rad-97 and Accessories is a multi-parameter patient monitor that is intended for multi-parameter physiological patient monitoring in hospital, hospital type facilities, mobile and home environments. The Rad-97 and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station).	The Masimo Rad-97 and Accessories are indicated for hospitals, hospital-type facilities, mobile, and home environments. The Masimo Rad-97 and Accessories can communicate with network systems for supplemental remote viewing and alarming (e.g., at a central station).	Same with addition of indications for spot-checking. The update in the indications for use for spot-checking was not found to result in a new intended use. The indications for use for the subject device have also been revised to include the cleared indications for the Respiratory Rate from photoplethysmogram (RRp) parameter

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	The Rad-97 and Accessories are indicated for the non-invasive spot-checking and continuous 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. The Rad-97 and Accessories are indicated for the non-invasive continuous monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions. The Rad-97 and Accessories are indicated for the non-invasive continuous monitoring of methemoglobin saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions. The Rad-97 and Accessories are indicated for the non-invasive continuous monitoring of total hemoglobin concentration (SpHb) of adult and	The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused.. The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of 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. 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. The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin	based on the subject device's clearance as part of K193242.

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	pediatric patients during no motion conditions. The Rad-97 and Accessories are indicated for the continuous monitoring of respiratory rate (RRa) for adult, pediatric, and neonatal patients during no motion conditions. In addition, the Rad-97 and Accessories are indicated to provide the non-invasive spot-checking and continuous monitoring data obtained from the 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 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 optional NomoLine Capnography product family is intended to be	saturation (SpMet) of adult, pediatric, and neonatal patients during no motion conditions. 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. 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 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.	

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<tr><th>Patient Population</th><th>Approximate Age Range</th></tr>
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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 Rad-97 and accessories are indicated for the non-invasive continuous monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) of adults during no motion conditions.

PVi may be used as a noninvasive dynamic indicator of fluid responsiveness in select populations of mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and

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 Rad-97 and accessories are indicated for the non-invasive continuous monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) of adults during no motion conditions

PVi may be used as a noninvasive dynamic indicator of fluid responsiveness in select populations of

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	should not be based solely on PVi. 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.	mechanically ventilated adult patients. Accuracy of PVi in predicting fluid responsiveness is variable and influenced by numerous patient, procedure and device related factors. PVi measures the variation in the plethysmography amplitude but does not provide measurements of stroke volume or cardiac output. Fluid management decisions should be based on a complete assessment of the patient's condition and should not be based solely on PVi.	
Principle of operation	*Masimo Rainbow SET Technology:* Noninvasive blood constituent measurements based on pulse oximetry principles and respiration rate measurement using acoustic signals. *Capnography Technology:* Respiratory gas measurement using infrared spectrometry *NiBP Technology:* Oscillometric measurement method	*Masimo Rainbow SET Technology:* Noninvasive blood constituent measurements based on pulse oximetry principles and respiration rate measurement using acoustic signals. *Capnography Technology:* Respiratory gas measurement using infrared spectrometry *NiBP Technology:* Oscillometric measurement method	Same
Display			
Display Type	Touchscreen LCD	Touchscreen LCD	Same

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Alarm			
Type of alarm	Visual/Audible alarm	Visual/Audible alarm	Same
Technological Characteristics			
Features	Pulse CO-Oximetry: SpO2, PR, Pi, PVi, RRp, SpMet, SpHb, SpCO, SpOC. Acoustic Respiration: RRa. NiBP: Systolic, Diastolic and MAP Capnography	Pulse CO-Oximetry: SpO2, PR, Pi, PVi, RRp, SpMet, SpHb, SpCO, SpOC. Acoustic Respiration: RRa NiBP: Systolic, Diastolic and MAP Capnography	Same
Performance			
SpO2, no motion	70-100%, 1.5%, adults /pediatrics/ infants/ neonates	70-100%, 1.5 % Arms, adults/ infants/ pediatrics; 3% neonates	Different. The specification for neonates has been revised to reflect the subject device's clearance as part of K191059.
SpO2, motion	70-100%, 1.5% Arms, adults/ infants/ pediatrics/ neonates	70-100%, 1.5 % Arms, adults/ infant/ pediatrics; 3% neonates	Different. The specification for neonates has been revised to reflect the subject device's clearance as part of K191059.
SpO2, low perfusion	70-100%, 2%, adults /pediatrics /infants /neonates	70-100%, 2%, adults/pediatrics/infants/ neonates	Same
Pulse rate, no motion	25-240 bpm, 3 bpm, adults/ infants/ pediatrics/ neonates	25-240 bpm, 3 bpm, adults/ infants/ pediatrics/ neonates	Same
Pulse rate, motion	25-240 bpm, 5 bpm, adults/ infants/ pediatrics /neonates	25-240 bpm, 5 bpm, adults/ infants/ pediatrics /neonates	Same
Pulse rate, low perfusion	25-240 bpm, 3 bpm, adults/ infants/ pediatrics	25-240 bpm, 3 bpm, adults/ infants/ pediatrics	Same
SpCO	1-40%, 3%, adults/ pediatrics/ infants	1-40%, 3%, adults/ infants/ pediatrics	Same

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SpMet	1-15%, 1%, adults/ infants/ pediatrics/ neonates	1-15%, 1%, adults/ infants/ pediatrics/ neonates	Same
SpHb	8-17 g/dL, 1g/dL adults/ pediatrics	8-17 g/dL, 1g/dL adults/ pediatrics	Same
RRa	4-70 rpm, 1 rpm, adults/pediatrics 4-120 rpm, 1 rpm, infants/neonates	4-70 rpm, 1 rpm, adults/pediatrics 4-120 rpm, 1 rpm, infants/neonates	Same
RRp	4-70 rpm, 3 rpm ARMS, 1 rpm Mean Error, adults/pediatrics	---	Different. The specification for neonates has been revised to reflect the subject device's clearance as part of K193242.
CO2	Single dry gasses at 22±5°C and 1013±40 hPa: 0-15 volume%: ± (0.2 volume% +2% or reading)	Single dry gasses at 22±5°C and 1013±40 hPa: 0-15 volume%: ± (0.2 volume% +2% or reading)	Same
Respiration rate	All conditions: ±(0.3 kPa + 4% of reading)	All conditions: ±(0.3 kPa + 4% of reading)	Same
NiBP	0 -300 mmHg, ISO 81060-2	0 -300 mmHg, ISO 81060-2	Same
Mode of Operation			
Mode of operation	Continuous operation	Continuous operation	Same

Feature	**Radical-7 Subject Device**	**Radical-7 Predicate device**	**Comparison to the predicate device**
510(k) Number	**K212161**	**K193242**	
General Information			
Primary Classification Regulation/ Product code	21 CFR 870.2700, Class II/DQA	21 CFR 870.2700, Class II/DQA	Same
Additional	21 CFR 862.3200, Class II/JKS	21 CFR 862.3200, Class II/JKS	Same

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Classification Regulation/ Product Code (s)	21 CFR 870.2710, Class II/DPZ 21 CFR 868.2375, Class II/BZQ	21 CFR 870.2710, Class II/DPZ 21 CFR 868.2375, Class II/BZQ	
Indications for Use	The Radical-7 and Accessories are indicated for the non-invasive spot-checking and continuous 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 non-invasive continuous monitoring of carboxyhemoglobin saturation (SpCO) of adult, pediatric, and infant patients during no motion conditions in hospitals and hospital-type facilities. The 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	The Masimo Radical-7® Pulse CO-Oximeter® and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radical-7® Pulse CO-Oximeter® and accessories are indicated for use with 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. In addition, the Masimo Radical-7® Pulse CO-Oximeter® and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical-7® Pulse CO-	Same with addition of spot-checking indications. The update in the indications for use for spot-checking was not found to result in a new intended use.

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	conjunction with additional methods of assessing clinical signs and symptoms. The Radical-7 and Accessories are indicated for the non-invasive continuous 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 non-invasive continuous 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 non-invasive continuous 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.	Oximeter® and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR) to multi-parameter devices for the display of those devices. 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.	

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	The Radical-7 and Accessories are indicated for the non-invasive continuous 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.		
Principle of operation	*Masimo Rainbow SET Technology:* Noninvasive blood constituent measurements based on pulse oximetry principles and respiration rate measurement using acoustic signals	*Masimo Rainbow SET Technology:* Noninvasive blood constituent measurements based on pulse oximetry principles and respiration rate measurement using acoustic signals	Same
Display			
Display Type	Touchscreen LCD	Touchscreen LCD	Same
Alarm			
Type of alarm	Visual/Audible alarm	Visual/Audible alarm	Same
Technological Characteristics			
Features	SpO2, PR, SpCO, SpMet, SpHb, RRa, RRp, Pi, PVi, SpOC, pleth waveform, alarm status, status messages, sensor status, Signal IQ	SpO2, PR, SpCO, SpMet, SpHb, RRa, RRp, Pi, PVi, SpOC, pleth waveform, alarm status, status messages, sensor status, Signal IQ	Same
Performance			
SpO2, no motion	70-100%, 2% adults/ pediatrics/ infants; 3% neonates	70-100%, 2% Arms, adults/ infants/ pediatrics; 3% neonates	Same
SpO2, motion	70-100%, 3% Arms, adults/ infants/	70-100%, 3 % Arms, adults/ infant/	Same

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	pediatrics/ neonates	pediatrics/ neonates	
SpO2, low perfusion	70-100%, 2%, adults/ pediatrics/ infants/ neonates	70-100%, 2%, adults/ pediatrics/ infants/ neonates	Same
Pulse rate, no motion	25-240 bpm, 3 bpm, adults/ infants/ pediatrics/ neonates	25-240 bpm, 3 bpm, adults/ infants/ pediatrics/ neonates	Same
Pulse rate, motion	25-240 bpm, 5 bpm, adults/ infants/ pediatrics /neonates	25-240 bpm, 5 bpm, adults/ infants/ pediatrics /neonates	Same
Pulse rate, low perfusion	25-240 bpm, 3 bpm, adults/ infants/ pediatrics / neonates	25-240 bpm, 3 bpm, adults/ infants/ pediatrics / neonates	Same
SpCO	1-40%, 3%, adults/ infants/ pediatrics	1-40%, 3%, adults/ infants/ pediatrics	Same
SpMet	1-15%, 1%, adults/ infants/ pediatrics/ neonates	1-15%, 1%, adults/ infants/ pediatrics/ neonates	Same
SpHb	8-17 g/dL, 1g/dL adults/ pediatrics	8-17 g/dL, 1g/dL adults/ pediatrics	Same
RRa	4-70 bpm, 1 rpm, adults/ pediatrics 4-120 bpm, 1 rpm, infants/ neonates	4-70 bpm, 1 rpm, adults/ pediatrics 4-120 bpm, 1 rpm, infants/ neonates	Same
RRp	4-70 rpm, 3 rpm ARMS, 1 rpm Mean Error, adults/pediatrics	4-70 rpm, 3 rpm ARMS, 1 rpm Mean Error, adults/pediatrics	Same
Respiration rate	0-150 breaths/min, 1 breaths/min	0-150 breaths/min, 1 breaths/min	Same
Mode of Operation			
Mode of operation	Continuous operation	Continuous operation	Same

4. Summary of Technological Characteristics of Subject Devices Compared to Predicate Devices

Similarities and Differences between Predicate and Subject Device –Rad-97 and Radical-7 with spot-checking feature

The subject devices, Rad-97 and Radical-7, and their respective predicate devices, Rad-97 (K193626) and Radical-7 (K193242), have the following key similarities:

- Same intended use;
- Same principles of operation and mechanism of action;
- Same measurement technologies;
- Same performance specifications

The subject devices, Rad-97 and Radical-7, and their respective predicate devices, Rad-97 (K193626) and Radical-7 (K193242), have the following key differences:

- The subject devices include the indication for spot-checking;

Between the subject devices and the predicates, the difference is the labeling update for the addition of the indication for spot-checking. The cleared versions of the subject devices already support both continuous monitoring and spot-checking use through the activation and deactivation of alarms. This submission updates the indications to reflect both uses of the subject devices.

As the subject devices are already able to be used without alarms, the addition of the indication for spot-checking is not a new intended use as compared to the predicates does not raise different questions of safety and effectiveness.

5. Performance Data

Biocompatibility Testing:

Rad-97 product family and Radical-7 are not intended for patient contact and do not include patient contacting materials. Therefore, biocompatibility testing is not applicable.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

Additional testing for Electromagnetic compatibility, Electrical Safety, Environmental, Mechanical and Cleaning chemical resistance was not needed to support the update to include spot-checking indications to subject devices.

Software Verification and Validation Testing

Software verification and validation testing were 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, as defined by the FDA guidance, *Guidance for Industry and FDA Staff – Pulse Oximeters - Premarket Notification Submissions [510(k)s],* dated March 3, 2013, 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 the substantial equivalence of the subject devices.

Cybersecurity and Wireless Testing

As part of this submission, there is no change to the interconnectivity of the Rad-97 and Radical-7 as compared to the previous cleared devices. As a result, no additional cybersecurity testing was conducted. The Rad-97 and Radical-7 are still considered a Tier 2 cybersecurity risk device in accordance with FDA draft guidance, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.* As such the previous cybersecurity risk mitigations were still considered applicable to support the substantial equivalence of the subject devices.

Human Factors Usability Testing

There are no product changes, including how the device can be used, as a result of the update indications to include spot-checking. The subject devices had already provided the capabilities to deactivate parameter alarms to support the spot-checking indications. As a result, no new Human factors and usability risk were found.

Non-clinical Testing

There are no product changes made to the subject devices other than the updated labeling to reflect the spot-checking indications. Therefore, non-clinical testing was not required for this submission.

Clinical Testing

There are no product changes made to the subject devices other than the updated labeling to reflect the spot-checking indications. Therefore, clinical testing was not required for this submission.

6. Conclusion

Provided the subject devices have the same intended uses, not changed by the addition of the spot-checking indications, and same technological characteristics they were found substantially equivalent to their respective predicate devices.