DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 14, 2017

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

Re: K170168
Trade/Device Name: Masimo 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, JKS, CCK, BZQ, DQA, DPZ, DXN, FLL
Dated: August 11, 2017
Received: August 14, 2017

Dear Marguerite Thomlinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170168

Device Name

Masimo Rad-97 and Accessories

Indications for Use *(Describe)*

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).

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Rad-97 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 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 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.

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 Rad-97 and Accessories, continued from page 1)

Indications for Use

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

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Section 5. 510(k) Summary

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Submitter:	Marguerite Thomlinson
Date:	August 11, 2017
Official Correspondent	Marguerite Thomlinson Senior Director, Regulatory Affairs Masimo Corporation Phone: (949) 297-7683 Mthomlinson@Masimo.com
Trade Name:	Masimo Rad-97/Rad-9 and Accessories
Common Name:	Oximeter
Primary Classification Regulation/ Product Code:	21 CFR 878.2300, Class II/MWI
Secondary Classification Regulation/ Product Code:	21 CFR 862.3220, Class II/JKS 21 CFR 880.2910, Class II/CCK 21 CFR 868.2375, Class II/BZQ 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:	New Device – Masimo Rad-97/Rad-9 and Accessories
Predicate Device:	K151644– Masimo Root Monitoring System and Accessories
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

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Device Description

The subject device, Masimo Rad-97 System and Accessories (Rad-97) product family, features a touchscreen display that continuously displays numeric values for the measured monitoring parameters. The Rad-97 product family can be operated on AC power or internally rechargeable battery.

The Rad-97 product family comprises the same measurement technologies as cleared in the predicate, Root (with connected external Radical-7 and capnography (ISA) and internal NIBP modules), which includes the Masimo Rainbow SET technology, capnography technology and noninvasive blood pressure (NIBP) technology. These technologies enable the Rad-97 product family to provide noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), 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 optional capnography parameters or optional noninvasive blood pressure (NIBP) parameters.

The Rad-97 product family is available with different measurement parameter configurations, ranging from a fully loaded configuration to a simplified configuration with pulse oximetry parameters only. In a fully loaded configuration, the Rad-97 model includes all parameters provided by the Masimo Rainbow SET technology including SpO2, PR, PI, PVI, SpCO, SpMet, SpHb, SpOC and RRa. Additionally, this fully loaded version can be optionally available with either NIBP or capnography technology.

The Rad-9 model, an instrument model within the Rad-97 product family, is an embodiment with a simplified configuration. The Rad-9 model includes the Masimo SET technology (a subset of Masimo Rainbow SET technology), which provides pulse oximetry parameters of SpO2, PR, PI and PVI. The Rad-9 model can be optionally available with NIBP technology.

Same as the predicate, the Rad-97 product family includes input/output interfaces for connection to external devices. Furthermore, same as the predicate, the Rad-97 product family can communicate through wired/wireless connection with networked systems such as Patient SafetyNet (K071047) and/or hospital electronic medical/health record (EMR) systems.

The RD SET Disposable Sensors, listed with other cleared accessories in Section 11.7, are the same as the currently marketed product. The only change is the added labeling

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information regarding the sensors' performance in terms of limits of agreement (LOA) as defined by Bland-Altman[1]

The table below provides the specifications for a fully loaded configuration of the Rad-97 instrument model with all parameters from the Masimo Rainbow SET technology and optional parameters from the Nomoline Capnography technology or optional parameters from the NIBP technology. The Rad-9 model, a simplified configuration of the Rad-97 product family, has the same instrument specifications but only includes pulse oximetry parameters from the Masimo SET technology, a subset of the Masimo Rainbow SET technology included in the Rad-97 model.

Feature	Rad-97 Specification
Display	
Display type	Touchscreen, Color LCD (Backlit Active Matrix TFT LCD)
Measurement range	Functional 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 (RRa): 0-70 breaths per minute
	Carboxyhemoglobin Saturation (SpCO): 0-99%
	Methemoglobin Saturation (SpMet): 0-99.9%
	Total Hemoglobin (SpHb): 0-25g/dL; 0-250g/L(0-15.52 mmol/dL)
	Oxygen Concentration (SpOC): 0-35ml of O_2/dL
	Carbon Dioxide (CO_2); 0 vol%-15 vol %
	End Tidal CO2 (EtCO2): 0-25 %, 0-32.5 kPa, 0-244 mmHg
	Fractional Inspired CO2 (FiCO2): 0-25 %, 0-32.5 kPa, 0-244 mmHg
	Respiratory Rate (RR): 0-150 breaths/min
	Adult, Systolic: 40-260 mmHg, Diastolic: 20-200 mmHg, MAP 26-220mmHg *Pediatric*, Systolic: 40-230 mmHg, Diastolic: 20-160 mmHg, MAP 26-183 mmHg *Neonatal*, Systolic: 40-130 mmHg, Diastolic: 20-100 mmHg, MAP 26-110mmHg
Display resolution	SpO_2: 1%
	PR: 1 bpm
	RRa: 1breath per minute
	SpCO: 1%
	SpMet: 0.1%
	SpHb: 0.1 g/dL
	SpOC: 0.1 ml/dL

[1] Bland and Altman. Agreement between methods of measurement with multiple observations per individual. Journal of Biopharmaceutical Statistics (2007) vol. 17 pp. 571-582 [Note: This paper was cited by Guidance for Industry and Food and Drug Administration Staff - Pulse Oximeters – Premarket Notification Submissions 510(k)s, March 4, 2013]

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Feature	Rad-97 Specification
Accuracy (ARMS)*	**Masimo Rainbow SET/ Masimo SET Parameters** [accuracy range , accuracy, patient population]
SpO2, no motion	60-80%, 3%, adults/pediatrics/infants
	70-100%, 2%, adults/pediatrics/infants 70-100%, 3%, neonates
	Upper 95% Limits of Agreement, 3% ** Lower 95% Limits of Agreement, -3%**
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 breaths per minute, 1 breath per minute for adults 4-70 breaths per minute, 1 breath per minute for 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/pediatrics
Accuracy	**Optional Capnography or Optional NIBP Parameters**
CO2	Single dry gasses at 22$\pm$ 5°C and 1013 $\pm$ hPa: 0-15 volume % $\pm$0.2 volume% +2% or reading All conditions: 0.3 kPa + 4% of reading
RR (Respiration rate)	0-150 breaths/min $\pm$ 1 breaths/min
NIBP	0-300 mmHg, $\pm$3 mmHg
Displays/ Indicators	
Data displayed	SpO_2, PR, SpCO, SpMet, SpHb, Rra, PI, PVI, SpOC, NIBP, CO_2, pleth waveform, alarm status, status messages, sensor status, Signal IQ, APOD, FastSat
Alarm	Alarm limits (audible and visual), 3D alarm, alarm silence, sensor condition alarms, system failure alarms, low battery alarms
Averaging time	SpO_2: 2-4, 4-6, 8, 10, 12, 14 and 16 seconds;
	Rra: Trending, No Averaging, Fast, Medium, or Slow
	PVI: Short or Long;
	PI: Short or Long;
	SpHb: Short, Medium, or Long
Sensitivity mode	Normal, APOD, and MAX
Sleep study mode	10 seconds
Electrical	
AC power	Input voltage: 100-240 VAC, 47-63 Hz; input power: 60 VA
Internal battery power	Rechargeable lithium ion battery
Input/Output Interface	
Patient applied part connection	M-20 connector Nomoline Capnography input connector NIBP Nib
Analog output	Nurse call output
USB interface	SatShare module and external devices (e.g. barcode reader/scanner) connection
Wired (Ethernet) and wireless (Wi-Fi/Bluetooth) interface	• Wired/wireless connection with networked Patient SafetyNet and/or EMR systems • Wireless connection with presence tag, Kite, external devices (e.g. Caregiver thermometer)
Camera (MIPI camera interface)	Surveillance/conferencing capabilities with Patient SafetyNet
Audio	Microphone supporting video/audio modes for surveillance/conferencing capabilities with Patient SafetyNet
Mechanical	
Enclosure Material	Thermoplastic

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Feature	Rad-97 Specification
Dimensions	9×4×6.5 inch (22.9×10.2×16.5cm)
Weight	< 1.36 kg. (3.0 lbs.) without Capnography and NIBP
Environmental	
Operating Temperature	0 to 35 ºC (32 to 95 ºF)
Storage/Transport Temperature	-20 to 60 ºC (-4 to 140 ºF)
Operating Humidity	10 to 95%, non-condensing
Storage/Transport Humidity	10 to 90%, non-condensing
Operating Atmospheric Pressure	540 to 1,060 mbar (540 to 1060 hPa)
Compliance	
Electrical Safety/EMC	IEC 60601 compliant
Type of Protection	Class 1, when on AC power; internally powered, when on battery power
Degree of Protection	Defibrillation proof, BF-applied part
Protection against harm from liquid ingress	IPX1, protection vertically falling water drops IPX2, protection against falling water drops when enclosure is tilted at 15 degrees
Mode of Operation	Continuous operation

*Accuracy in term of root mean square (A_{RMS}) is a statistical calculation of the difference between device measurements fell within +/- A_{RMS} of the reference measurements in a controlled study.
**Upper and lower limits of agreement specifications have been validated in clinical study on healthy adult volunteers, with RD SET Disposable Sensors and Masimo Rainbow SET technology.

Intended Use/Indications for Use

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).

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Rad-97 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 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 (SpO_2) and pulse rate (PR) to multi-parameter devices for the display on those devices.

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 optional Nomoline Capnography product family is intended to be connected to other medical backboard devices for monitoring of breath rate and CO_2. 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

Technological Characteristics

Principle of Operation – Masimo Rainbow SET/ Masimo SET Technology

Optical Measurements (SpO2, Pulse Rate, SpCO, SpMet, SpHb, PI, PVI, SpOC) – The Masimo Rainbow SET technology utilizes the general principles of pulse oximetry for noninvasive optical measurements of SpO2, pulse rate, SpCO, SpMet and SpHb measurements. The perfusion index (PI), pleth variability index (PVI) and oxygen (SpOC) values are derived from these measurements. While the Masimo Rainbow SET technology includes all the above optical measurements, a subset of that technology, the Masimo SET technology, includes pulse oximetry measurements for SpO2, pulse rate, PI and PVI.

The Masimo Rainbow SET/ Masimo SET technology is governed by the following principles:

- Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).

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- The amount of arterial blood in tissue changes with pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

The Masimo Rainbow SET technology uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma.

Acoustic Measurement (RRa) – The Masimo Rainbow Acoustic Monitoring (RAM) technology uses acoustic signals for respiration rate (RRa) measurements. RRa measures a patient's respiration rate based on airflow sounds generated in the upper airway. RRa translates airflow sounds generated in the upper airway to an electrical signal that can be processed to produce a respiration rate, measured as breaths per minute.

Principle of Operation – Capnography

The measurement of CO_2 is based on the fact that different gases absorb infrared light at specific wavelengths. The analysis of respiratory gases is therefore performed by continuously measuring the infrared light absorption in the gas flow through an infrared spectrometer.

The infrared spectrometer uses a proprietary broadband infrared radiation source to transmit light through the gas sample. Before reaching the gas sample, the light path is intersected by narrowband optical filters that only let through light corresponding to selected wavelength peaks of the measured gases. At the other end of the light path, a sensor detects the portion of the light that is not absorbed by the gas. The amplitude of the detector output is an inverse function of the gas concentration. Thus, at a concentration of zero, the amplitude is at its maximum.

If the gas sample is a mixture of several components that absorb light at the same wavelength, such as a mixture of two anesthetic agents, the absorbed radiation will be the sum of the absorption of the agents. To determine the concentration of each of the individual gases, several filters have to be used. The spectrometer contains up to nine different narrowband filters to facilitate simultaneous measurement of different gases or a mixture of two gases.

Principle of Operation – Noninvasive Blood Pressure (NIBP)

The oscillometric method of blood pressure measurement is a non-invasive method that monitors the amplitude of cuff pressure changes during cuff deflation to

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determine arterial blood pressure. The cuff pressure is first elevated above the patient systolic blood pressure level and the cuff begins to deflate at a certain rate. The initial rise in amplitude of these pressure fluctuations during cuff deflation corresponds closely to the systolic blood pressure. As the cuff is further deflated, these pressure fluctuations increase in amplitude until a peak is reached which is usually referred to as the mean arterial pressure (MAP). As cuff deflation continues, the diastolic pressure can be determined based upon the rapidly diminishing amplitude of the pressure fluctuations. Thus systolic, MAP and diastolic blood pressures can be accurately obtained by supervising the pressure fluctuations while controlling the cuff deflation rate.

Mechanism of Action for Achieving the Intended Effect

The device is turned "on" for its operation.

One end of a patient applied part (e.g. patient cable and SpO2 sensor, capnography sampling line) is connected to the subject device, and the other end of the patient applied part is connected to the patient. Physiological signals collected via patient applied part are sent to the subject device for processing. The subject device then displays the processed signals or measurements.

Data input devices (e.g. barcode scanner) can be used to enter patient identification information to associate the monitor to a patient. Data originating from a third party device can be displayed and transferred through the subject device onto a compatible surveillance monitoring system such as Patient SafetyNet (K071047) and/or EMR systems.

The optional microphone and camera can be used with compatible audio/video conferencing system. When configured with the optional Kite software, the display on the subject device can be re-displayed in near real time on a secondary display.

Once use is complete, the user then turns the power "off" in the device.

Summary of Technological Characteristics of Subject Device Compared to Predicate

The subject device, Rad-97 product family, and the primary predicate device, Root, have the following key similarities:

- both have the same intended use as patient monitoring device;

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- both have the same principle of operation, mechanism of action for Masimo and performance specifications for Masimo Rainbow SET, capnography and NIBP technologies;
- both have same input/output interfaces (e.g. USB, patient-applied part interface, wired/wireless connection) that allows connection with external devices and with networked systems;
- both are compatible with the same applied patient parts (e.g. sensors, blood pressure cuffs);
- both have the same SatShare feature

The subject device, Rad-97 product family, and the primary predicate device, Root, have the following key differences:

- the subject device, with Masimo Rainbow SET and NIBP technologies, is intended to be used in healthcare and home environments; whereas the predicate is only intended to be used in healthcare environments [Note, the Radical-7 module for the predicate is the same as the Radical-7 (K110028) as a standalone device indicated for home and hospital use]
- the subject device comprises Masimo Rainbow SET, capnography and NIBP technologies; whereas the predicate comprises Sedline and body temperature technologies in addition to those included in the subject device; and
- the subject device does not have docking and MOC-9 interfaces that are included with the predicate.

Non-clinical Testing

The following tests, as applicable, were performed for the qualification of the subject device, Rad-97 product family, in accordance with the requirements of the design control regulations and established quality assurance processes to demonstrate substantial equivalence with its predicates:

- Electrical safety testing per IEC-60601-1
- EMC testing per IEC-60601-1-2
- Usability testing per FDA Human Factors and Usability Draft Guidance
- Software verification, including integration testing with host monitors, per FDA Software Guidance
- Mechanical testing per ISTA-2A and MIL-STD 810E
- Environmental testing per IEC-60601-1

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Clinical Testing

To obtain the limits of agreement (LOA) information for the RD SET Disposable Sensors, a clinical study was performed in accordance with ISO-80601-2-61. The study was done on healthy adult volunteers to evaluate the sensor's performance for no motion condition, in the range of 70% to 100% in comparison to blood measurements from a laboratory CO-Oximeter. Using the Bland-Altman method, the mean difference between two methods of measurements (the 'bias') and 95% LOA as the mean difference, two standard deviations, (2 SD) [or more precisely (1.96 SD)] was calculated. In this case, the 95% LOA calculation was between the noninvasive arterial oxygen (SpO2) measurements using RD SET Sensors and invasive measurements (blood draws). See the table below for a summary of the clinical results.

	LOA (Results)	**LOA (Requirement)**
Upper 95% LOA	3.15%	$\leq$ 3%
Lower 95% LOA	-2.21%	$\geq$ -3%

Conclusion

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