December 27, 2019

Masimo Corporation
Linus Park
Vice President, Regulatory
52 Discovery
Irvine, California 92618

Re: K191059
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, DQA, DPZ, DXN, CCK, BZQ, FLL
Dated: November 26, 2019
Received: November 27, 2019

Dear Linus Park:

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)*
K191059

Device Name
Masimo Rad-97 and Accessories

Indications for Use *(Describe)*
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 multiparameter 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 in hospitals, hospital-type facilities, mobile, and home environments. 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

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

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	December 27, 2019
Contact:	Linus Park Vice President, Regulatory Affairs Masimo Corporation Phone: (949) 297-7337
Trade Name:	Masimo 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 868.1400, Class II/CCK 21 CFR 862.3220, Class II/JKS 21 CFR 868.2375, Class II/BZQ 21 CFR 870.1130, Class II/DXN 21 CFR 880.2910, Class II/FLL
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Apply the previously cleared SpO2 performance specification to the neonate population
Predicate Device:	K180046 – Masimo Rad-97 and Accessories
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

5.1. 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 internal rechargeable battery.

The subject device (Rad-97 product family) is substantially the same as the predicate (Rad-97 product family) cleared under K180046, and has the same indications for use. The Rad-97 comprises of the same measurement technologies as cleared in the predicate, 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

Section 5. 510(k) Summary

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 optional capnography parameters or optional noninvasive blood pressure (NIBP) parameters.

The subject of this submission is the update to the SpO2 performance specification for the RD SET Disposable sensors for the neonate population to match that of the cleared 1.5% Arms for adults (K180046).

The specifications for Rad-97 are as follows:

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
Accuracy (A_{RMS})*	**Masimo Rainbow SET/ Masimo SET Parameters**
SpO_2, no motion	70-100%, 1.5%, adults/pediatrics/infants/neonates**
SpO_2, motion	70-100%, 1.5% adults/pediatrics/infants/neonates**

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Feature	Rad-97 Specification
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, 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/pediatrics
Accuracy	**Optional Nomoline Capnography or Optional NIBP Parameters**
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 breaths/min ± 1 breaths/min
NIBP	0-300 mmHg, ±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

Section 5. 510(k) Summary

Feature	Rad-97 Specification
Audio	Microphone supporting video/audio modes for surveillance/conferencing capabilities with Patient SafetyNet
Mechanical	
Enclosure Material	Thermoplastic
Dimensions	9×4×6.5 inch (22.9×10.2×16.5cm)
Weight	0.92 kg. (2.03 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 Non NiBP/Nomoline Capnography	10% to 95%, non-condensing
Operating Humidity NiBP/Nomoline Capnography	15% to 95%, non-condensing
Storage/Transport Humidity Non NiBP/Nomoline Capnography	10% to 90%, non-condensing
NiBP/Nomoline Capnography	15% to 90% non-condensing
Operating Atmospheric Pressure Non-NiBP/ Nomoline Capnography	540 mbar to 1,060 mbar (540 hPa to 1060 hPa)
Nomoline Capnography	525 mbar to 1,200 mbar (525 hPa to 1200 hPa) (corresponding to a max altitude of 4572 m / 15 000 feet)
Compliance	
Electrical Safety/EMC	IEC 60601 compliant
Type of Protection	Class I, 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

**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.*

*** Applicable to compatible sensors. A_{RMS} validated in healthy adult volunteer subjects. See Section 5.5.5 for real world performance data collected in neonatal patients.*

Note: RD SET Disposable sensors are same as RD SET Adhesive sensors. In order to be consistent with the clearance obtained under K180046 and also the current branding (Directions for Use) for the sensors,

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Section 5. 510(k) Summary

510k summary has been revised to reflect the subject of the submission as RD SET Disposable sensors in place of RD SET Adhesive sensors.

5.2. Intended Use/ Indications for Use

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 multiparameter devices for the display on those devices.

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The optional non-invasive blood pressure (NIBP) module is indicated for the noninvasive measurement of arterial blood pressure in hospitals, hospital-type facilities, mobile, and home environments. The NIBP module is designed to measure blood pressure for patient population described in the following table:

Section 5. 510(k) Summary

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

5.3. Technological Characteristics

Principle of Operation

The principle of operations for the measurement capabilities of the Rad-97 product family does not change from the predicate (K180046) for the update to the RD SET Disposable sensor specifications for the neonate population. The principles of operation are still based upon the use of red and infrared wavelengths of light provided by an emitter and the detection of the signal from the light absorption of oxygenated blood and deoxygenated blood to provide functional oxygen saturation of hemoglobin (SpO_2).

Mechanism of Action for Achieving the Intended Effect

The mechanism of action did not change from the predicate. The sensor is applied in the same way and to the same measurement sites as the predicate.

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

The only difference between the subject device and the predicate is the SpO2 performance specification is updated to match that as it was previously cleared for the adult population as part of the predicate. There are no other difference between the predicate RD SET Disposable sensors to that of the subject device.

The subject device, RD SET Adhesive sensors with updated SpO2 specifications for the neonate population and the predicate device, have the following key similarities:

- Both devices have the same indicated populations;
- Both sensors have the same form factor and components;
- Both sensors have the same measurement application sites

The subject device, RD SET Adhesive sensor with update SpO2 performance specifications for the neonate population and the predicate device, have the following difference:

- Subject device has an updated SpO2 performance specification of 1.5% Arms. The SpO2 specification is being updated to match the adult population SpO2 performance specification previously cleared as part of the predicate.

5.5. Performance Data

As part of this submission, there were no physical changes to the RD SET Disposable sensor. The

Section 5. 510(k) Summary

changes was to the update of the labeling to align the performance specification for the neonate population to that of the adult population.

5.5.1. Biocompatibility Testing

As there were no changes associated with this submission, no additional biocompatibility testing was required to support the substantial equivalence.

5.5.2. Electrical Safety and EMC

As there were no hardware changes associated with this submission, no additional electrical safety or EMC testing was required to support the substantial equivalence.

5.5.3. Software Verification and Validation Testing

As there were no software changes associated with this submission, no additional software verification and validation testing was required to support the substantial equivalence.

5.5.4. Mechanical Testing

As there were no mechanical changes associated with this submission, no additional mechanical testing was required to support the substantial equivalence.

5.5.5. Clinical Testing

As part of the submission, there was no changes made to the devices from the previous clearance in which the accuracy performance of the RD SET Disposable sensors was established to be 1.5% Arms validated on adults. As part of this submission, Masimo performed clinical testing on neonates using convenience arterial blood samples in accordance with the FDA guidance for Pulse Oximeters to verify the form, fit, and function of the RD SET Disposable sensors on neonate population. Although the RD SET Disposable sensors are not new or significantly modified the convenience samples were collected on neonatal population in order to provide greater assurance of the safe form, fit, and function on neonates.

As part of the study, convenience blood samples were collected from an arterial line of 19 neonatal subject's that were ≤ 1 month and weighing ≤ 4.5 kg. The SaO2 measurements from the blood samples using a reference co-oximeter were compared to the SpO2 measurements using a RD SET Disposable sensor. As the convenience blood samples were collected in a clinical environment dependent upon the availability of subjects, the results were subject to greater amounts of testing variability than would be expected in a controlled laboratory setting.

The analysis of the clinical data further supported the safe form, fit, and function of the RD SET Disposable Sensor on neonates. The Arms performance was calculated for reference purposes. See summary of Arms performance in table 5.5.1 below.

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Table 5.5.1				
SaO2	**Bias**	**Precision**	**RMS**	**Subjects**
70-100%	0.08	2.58	2.59	19
85-100%	-0.09	1.39	1.40	12
70-85%	0.37	3.83	3.85	7

To further support the safe form, fit, and function of the RD SET Disposable sensor on neonates, additional convenience arterial blood samples collected on neonates using the subject sensor from prior studies were aggregated with the data from the above study resulting in 70 data pairs collected on 42 subjects (including 22 Pre-term neonates with gestational ages ≤ 37 weeks) from 3 different sites. See summary of the observed results in table 5.5.2 below.

Table 5.5.2							
Description	**Age (days)**	**Gest. Age (weeks)**	**No. Subjects**	**Samples**	**Bias**	**Precision**	**A_{RMS}**
All Data	1-31	27-41	42	70	0.129	3.182	3.185

The results of the clinical testing supported the subject device did not raise any different questions of safety and effectiveness as compared to the predicate device.

5.6 Conclusion

The data supports the substantial equivalence of the subject device with the predicate.