October 23, 2018

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

Re: K180046
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, FLL, DQA, DPZ, DXN, CCK, BZQ
Dated: September 12, 2018
Received: September 21, 2018

Dear Sindura Penubarthi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K180046

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.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Submitter:	Sindura Penubarthi
Date:	October 22nd 2018
Official Correspondent	Sindura Penubarthi Regulatory Affairs Manager Masimo Corporation Phone: (949) 297-7541 spenubarthi@masimo.com
Trade Name:	Masimo Rad-97 and Accessories
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 878.2300, Class II/MWI
Additional Product Code:	21 CFR 870.2700, Class II/DQA 21 CFR 880.2910, 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
Establishment Registration Number:	2031172
Reason for Premarket Notification:	New Device – Masimo Rad-97 and Accessories
Predicate Device:	K170168 – Masimo Rad-97 and Accessories
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

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 subject device (Rad-97 product family) is substantially the same as the predicate (Rad-97 product family) cleared under K170168, and has the same indications for use. The Rad-97 comprises 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 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-9, an instrument model within the Rad-97 product family, is an embodiment with a simplified configuration. The Rad-9 was also cleared in K170168. The Rad-9 model includes the Masimo SET technology (a subset of Masimo Rainbow SET technology), which provides pulse oximetry parameters of SpO_2, PR, Pi, and PVi. The Rad-9 model can be optionally available with NIBP technology.

Masimo's Rad-97 has improved SpO_2 measurement accuracy for motion and no motion conditions with RD SET Disposable sensors previously cleared under K170168. Masimo improved its RD SET Disposable sensors through sensor characterization, facilitating a SpO_2 measurement accuracy claim of 1.5% A_{rms} during no-motions conditions for patient populations (adults, pediatrics, infants, and neonates) when used with Masimo's MX/MS-2000 boards. Masimo's SpO_2 measurement accuracy claim with RD SET Disposable Sensors is 1.5% A_{rms} during motion conditions for patient population (adults, pediatrics, infants, and neonates) when used with Masimo's MX/MS-2000 boards. Although they now include improved sensor characterization, the RD SET Disposable sensors are substantially equivalent to the currently marketed product.

Additionally, this submission includes the following sensors that have non-significant changes: the Multisite Reusable Sensors (K111888), the RD Specialty Sensors (K101896), and the RD reusable sensors (K051212).

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

The table below provides the specifications for a fully loaded configuration of the Rad-97 instrument model with all parameters.

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** 70-100%, 3%, neonates
SpO_2, motion	70-100%, 1.5% adults/pediatrics/infants** 70-100%, 3%, neonates
SpO_2, low perfusion	70-100%, 2%, adults/pediatrics/infants/neonates
Pulse rate, no motion	25-240 bpm, 3 bpm, adults/pediatrics/infants/neonates
Pulse rate, motion	25-240 bpm, 5 bpm, adults/pediatrics/infants/neonates
Pulse rate, low perfusion	25-240 bpm, 3 bpm, adults/pediatrics/infants/neonates
RRa	4-70 breaths per minute, 1 breath per minute, adults/pediatrics

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

Feature	Rad-97 Specification
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
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	

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

Feature	Rad-97 Specification
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*

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.

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.

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

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

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

Patient Population	Approximate Age Range
Adolescent	12-21 years of age
Adult	21 years of age and older

Technological Characteristics

The Rad-97 principle of operation for Masimo SET/Masimo Rainbow SET technology is the same as the predicate (K170168). This section addresses the additional features of this submission.

The Masimo Rainbow SET technology utilizes the general principles of pulse oximetry for noninvasive optical measurements. Specifically, 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.

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 SpO_2 sensor) 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.

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 predicate device, Rad-97, have the following key similarities:

- both have the same intended use as patient monitoring device;
- both have the same principle of operation, mechanism of action, and similar performance specifications;
- 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; and
- both are compatible with the same applied patient parts (e.g. sensors, blood pressure cuffs).

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

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

- The subject device claims a SpO_2 measurement accuracy of 1.5% Arms during no-motions conditions for patient populations (adults, pediatrics, and infants) when used with RD SET Disposable sensors;
- The subject device claims a SpO_2 measurement accuracy of 1.5% Arms during motion conditions for patient population (adults, pediatrics, and infants) when used with RD SET Disposable Sensors.

Non-clinical Testing

The subject device Rad-97 is substantially the same as the predicate cleared under K170168. Non- clinical testing was performed to demonstrate substantial equivalence.

The following non-clinical testing was performed on subject device Rad-97.

- Software verification, including integration testing with host monitor for additional features, per FDA software guidance.
- Electrical safety testing per IEC-60601-1
- EMC testing per IEC-60601-1-2
- Alarm testing per IEC-60601-1-8
- Biocompatibility testing per ISO-10993
- Mechanical and Environmental Testing per IEC 60601-1 and ISO 80601-2-61
- Pulse rate accuracy for the range of 25-240 bpm in performance bench testing against a Biotek Index 2 Simulator.

Clinical Testing

To obtain the accuracy (RMS) of the RD SET Disposable sensors during no-motion and motion conditions, 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 and motion conditions, in the range of 70% to 100%, in comparison to blood measurements from a laboratory CO-Oximeter. The repeated measure adjusted results were as follows:

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

% SpO_2 No Motion Accuracy		
Bias	Adjusted Precision	Adjusted RMS
-0.01%	1.16%	1.16%

% SpO_2 Motion Accuracy		
Bias	Adjusted Precision	Adjusted RMS
0.33%	1.27%	1.31%

Accordingly, the claimed A_{rms} value is 1.5% during no-motion conditions for adults, pediatrics, and infants, and the claimed A_{rms} value is 1.5% during motion conditions for adult, pediatrics, and infants.

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.