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

Re: K183697
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: April 15, 2019
Received: April 16, 2019

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,

for Michael Ryan
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

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)*
K183697

Device Name
Masimo Rad-97 with 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

The optional Masimo Centroid O2 is intended for the non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).

The optional Masimo Centroid O2 is indicated for the continuous monitoring of functional arterial oxygen saturation of hemoglobin (SpO2) and pulse rate (PR) 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 hospital, hospital-type facilities and home environments.
Devices with Masimo technology are only to be used with Masimo sensors and cables.

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."

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, 2018
Contact:	Sindura Penubarthi Regulatory Affairs Manager Masimo Corporation Phone: (949) 297-7541
Trade Name:	Masimo Rad-97 and Accessories
Common Name:	Patient Monitor
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 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:	New Device
Predicate Device:	K180046 – Masimo Rad-97 and Accessories
Reference Predicate:	K153225 – Masimo Root Monitoring System 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

Section 5. 510(k) Summary

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 subject of this submission, is the inclusion of Masimo Centroid O2 sensor to be used with the Rad-97 and similar devices that utilize Masimo SET technology.

The Centroid O2 is a family of wearable, battery operated, sensors that support Masimo SET technology. The Centroid O2 uses wireless communication to a host device (e.g., Rad-97, Radical-7) in order to support the continuous monitoring of Masimo SET parameters (SpO_2 and PR). Centroid O2, similar to the previously cleared RD SET sensors (K180046), are intended for the noninvasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR).

The Centroid O2 consists of both disposable and reusable components. The disposable components include the sensor and wrist strap; the reusable component contains the hardware to transfer the measured data wirelessly. Centroid O2 uses a battery as a power source for the sensor and to enable measurement data to be transferred wirelessly to a host device (e.g. Rad-97, Radical-7).

The specifications for Rad-97 are as follows:

Feature	Rad-97 Specification
Display	
Display Type	Touchscreen, Color LCD (Backlit Active Matrix TFT LCD)
Measurement Display 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

Section 5. 510(k) Summary

Feature	Rad-97 Specification
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%, 2%, adults/pediatrics/infants 70-100%, 3%, neonates
SpO_2, motion	70-100%, 3% adults/pediatrics/infants/neonates
SpO_2, low perfusion	70-100%, 2%, adults/pediatrics/infants 70-100%, 3%, 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 Limits of Agreement (LOA) over a range of 8-17 g/dL	-1.83 to 1.57 g/dL
Accuracy	**Optional Nomoline 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
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

Section 5. 510(k) Summary

Feature	Rad-97 Specification
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	
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 per IEC 60601-1	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.*

The specifications for Centroid O2 are as follows:

Feature	Centroid O2 Specification
Accuracy (A_{RMS})*	**Masimo SET Parameters**
SpO_2, no motion	70-100%, 2%, adults/pediatrics/infants 70-100%, 3%, neonates
SpO_2, motion	70-100%, 3% adults/pediatrics/infants/neonates
SpO_2, low perfusion	70-100%, 2%, adults/pediatrics/infants

Section 5. 510(k) Summary

Feature	Centroid O2 Specification
	70-100%, 3%, 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
Mode of Operation per IEC 60601-1	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.*

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.

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

Section 5. 510(k) Summary

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

The optional Masimo Centroid O2 is intended for the non-invasive continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).

The optional Masimo Centroid O2 is indicated for the continuous monitoring of functional arterial oxygen saturation of hemoglobin (SpO2) and pulse rate (PR) 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 hospital, hospital-type facilities and home environments.
Devices with Masimo technology are only to be used with Masimo sensors and cables.

5.3. Technological Characteristics

Principle of Operation

The principle of operations for the measurement capabilities of the Rad-97 product family with Centroid O2 does not change from the predicate (K180046). 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).

In regards to the wireless transfer of data to a host device (e.g. Rad-97, Radical-7), the Rad-97 with Centroid O2 uses the same principle of operation as the reference predicate, Root with Radius-7 (K153225). The transferred data can then be used by the host device (e.g. Rad-97, Radical-7) to display and provide monitoring similar to the reference predicate, Root with Radius-7.

Mechanism of Action for Achieving the Intended Effect

The mechanism of action for the Rad-97 with the Centroid O2 involves the application of sensor

Section 5. 510(k) Summary

emitter and detector of the Centroid O2 to the measurement site similar to the primary predicate. The sensor is then secured to the patient using the integral strap provided with the sensor, similar to the reference predicate.

To start the wireless communication from the host device (e.g. Rad-97, Radical-7) to the Centroid O2, the reusable module is paired to the wireless receiver connected to the host device, similar to reference predicate. Once the pairing operation is completed, the reusable module is connected to sensor to begin the measurement and communication of the measurement to the host device for display and monitoring. The Centroid O2 will securely pair with the wireless receiver upon successful confirmation that device is valid.

Upon successful secure wireless connection of Centroid O2 System with the host device (e.g., Rad-97, Radical-7), measurement data collected via the Centroid O2 is sent to the host device for display and monitoring, similar to the predicates.

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

Similarities and Differences between Predicate and Subject Device

The subject device, Masimo Rad-97 and Accessories (Centroid O2) and the predicate device, Masimo Rad-97 and Accessories (RD SET sensor) (K180046), have the following key similarities:

- Both devices utilize Masimo SET and Rainbow SET Technology;
- Both devices have the same intended use as a patient monitoring device;
- Both devices have the same performance specifications;
- Both devices have the same input/ output interfaces that allows connection with external devices and with networked systems;
- Both sensors continuously monitor and report patient activity to the host device;
- The subject sensor includes wireless technology to connect to a host/backbone device, similar to the reference predicate Radius-7 cleared under K153225;
- The subject sensor is internally powered by a battery module similar to the reference predicate Radius-7 cleared under K153225.

The subject device, Masimo Rad-97 with Centroid O2 System, and the predicate device, Masimo Rad-97 and Accessories (K180046), have the following key differences:

- Both devices have similar indications for Use; however, the subject device includes addition of Centroid O2 to the existing indications

5.5. Performance Data

Biocompatibility Testing:

Section 5. 510(k) Summary

Rad-97 product family is not intended for patient contact, thus the device does not include patient contacting materials. Therefore, biocompatibility testing is not applicable.

The Centroid O2 includes a single patient use adhesive sensor that includes patient contacting materials. These materials have been evaluated for biocompatibility and are compliant to ISO-10993. Testing performed and submitted supports the biocompatibility testing for the patient contacting materials.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

Testing was performed and submitted with respect to the EMC compliance to IEC 60601-1-2, Electrical Safety compliance to IEC 60601-1, environmental, mechanical, and cleaning chemical resistance. The testing was found to support the substantial equivalence of the subject device.

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 device.

Wireless and Cybersecurity Testing

As the subject device uses wireless communication between the Centroid O2 to the wireless receiver attached to host device (e.g., Rad-97, Radical-7) wireless and cybersecurity considerations were made in accordance with FDA *Guidance for Industry and Food and Drug Administration Staff- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,* dated October 2, 2014 and draft guidance dated October 18, 2018. In accordance with the FDA guidance for Cybersecurity, the Rad-97 with Centroid O2 was considered a tier 2 device. A risk-based assessment and testing in accordance with referenced FDA guidance documents were conducted. The testing was found to support the substantial equivalence of the subject device.

Human Factors Usability Testing

Human factors and usability risk were evaluated and acceptably mitigated in accordance

Section 5. 510(k) Summary

with FDA Guidance, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design*, dated February 3, 2016. The testing was found to support the substantial equivalence of the subject device.

Non-clinical Testing

To support the substantial equivalence of the subject device, the following non-clinical bench testing was performed on the subject device Rad-97 with Centroid O2.

- Electrical safety testing per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Usability testing per FDA Human Factors and Usability Guidance
- Software verification and validation testing per FDA Software Guidance
- Biocompatibility testing per ISO-10993
- Mechanical testing per IEC 60601-1 and ISO 80601-2-61

The non-clinical testing was conducted in accordance with Masimo requirements to ensure that the specifications of the subject device were met. The testing was found to support the substantial equivalence of the subject device.

Clinical Testing

To establish the accuracy (A_{RMS}) of the Centroid O2 sensors during no-motion and motion conditions, a clinical study was performed in accordance with ISO 80601-2-61. The study was done, as prescribed by the ISO 80601-2-61 standard, on healthy adult volunteers to evaluate the sensor's performance for no motion and motion conditions, in the range of 70% to 100% SaO2, in comparison to blood measurements from a laboratory CO-Oximeter. The results adjusted for the repeated measurements were as follows:

% SpO_2 No Motion Accuracy		
Bias	Adjusted Precision	Adjusted RMS
-0.5	1.2	1.3

% SpO_2 Motion Accuracy		
Bias	Adjusted Precision	Adjusted RMS
-0.9	2.0	2.2

Accordingly, the A_{rms} value is 2% during no-motion conditions, and the A_{rms} value is 3% during motion conditions.

Section 5. 510(k) Summary

5.8 Conclusion

The non-clinical and clinical data support the substantial equivalence of the Rad-97 with Centroid O2.