August 10, 2020

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

Re: K193626
Trade/Device Name: Masimo Rad-97 Pulse CO-Oximeter 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, CCK, DPZ, DXN, FLL, BZQ
Dated: July 28, 2020
Received: July 29, 2020

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,

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)*

K193626

Device Name

Masimo Rad-97 Pulse CO-Oximeter 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) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of pulse rate (PR) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

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

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

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

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

In addition, the Masimo Rad-97 and Accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Rad-97 and Accessories for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) to multi-parameter devices for the display on those devices.

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.

The optional non-invasive blood pressure (NIBP) module is indicated for the noninvasive measurement of arterial blood pressure. The NIBP module is designed to measure blood pressure for patient population described in the following table:

Patient Population Approximate Age Range
Newborn (neonate) Birth to 1 month of age
Infant 1 month to 2 years of age
Child 2 to 12 years of age
Adolescent 12-21 years of age
Adult 21 years of age and older

Devices with Masimo technology are only indicated for use with Masimo sensors and cables.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) for adults and pediatrics during no motion conditions in hospitals and hospital-type facilities.

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

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.

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
Date:	July 28, 2020
Contact:	Linus Park Vice President, Regulatory Masimo Corporation Phone: (949) 297-7337
Trade Name:	Masimo Rad-97 Pulse CO-Oximeter and Accessories
Common Name:	Oximeter.
Classification Regulation/ Product Code:	21 CFR 870.2300, Class II/MWI
Additional Product Code:	21 CFR 870.2700, Class II/DQA 21 CFR 862.3200, Class II/JKS 21 CFR 880.2910, Class II/CCK 21 CFR 870.2710, Class II/DPZ 21 CFR 870.1130, Class II/DXN 21 CFR 880.2910, Class II/FLL 21 CFR 868.2375, Class II/BZQ
Establishment Registration Number:	2031172
Reason for Premarket Notification:	Expanded indications for PVi
Predicate Device:	K183697 – 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

Masimo Rad-97 System and Accessories (Rad-97 product family), features a touchscreen display that continuously displays numeric values for the connected 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 the same as the predicate (Rad-97 product family) cleared under K183697. 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 saturation of arterial hemoglobin (SpO2), pulse rate (PR), Pleth Variability Index (PVi), carboxyhemoglobin (SpCO), methemoglobin (SpMet), total

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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 addition of indications for PVi, an index previously cleared as an informational index.

General Information	
Display	
Display Type	Touchscreen LCD
Alarm	
Type of alarm	Visual/Audible alarm
Technological Characteristics	
Measured Parameters	NIBP, SpO2, PR, SpCO, SpMet, SpHb, RRa, Pi, CO2
Calculated or Derived Parameters	PVi
Performance Specification	
SpO2, no motion	70-100%, 1.5%, adults/pediatrics/infants 3% neonates
SpO2, motion	70-100%, 1.5% Arms ,adults/ infants/ pediatrics; 3% neonates
SpO2, low perfusion	70-100%, 2%, adults/pediatrics/infants/neonates
Pulse Rate, no motion	25-240 bpm, 3 bpm, adults/ infants/ pediatrics/ neonates
Pulse Rate, motion	25-240 bpm, 5 bpm, adults/ infants/ pediatrics /neonates
Pulse Rate, low perfusion	25-240 bpm, 3 bpm, adults/ infants/ pediatrics / neonates
SpCO	1-40%, 3% , adults/ infants/ pediatrics
SpMet	1-15%, 1% , adults/ infants/ pediatrics/ neonates
SpHb	8-17 g/dL, 1g/dL adults/ pediatrics
RRa	4-70 rpm, 1 rpm, adults/pediatrics 4-120 rpm, 1 rpm, infants/neonates
CO2	Single dry gasses at 22±5°C and 1013±40 hPa: 0-15 volume %: ±(0.2 volume% +2% or reading)
	All conditions: ±(0.3 kPa + 4% of reading)
NIBP	0-300 mmHg, ISO 81060-2
Environmental	
Operating temperature	0 to 35 ºC (32 to 95 ºF)
Storage temperature	-20 to 60 ºC (-4 to 140 ºF)
Operational/ storage humidity	10 to 95%, non-condensing
Operating atmospheric pressure	540 mbar to 1,060 mbar (540 hPa to 1060 hPa)
Mechanical	
Instrument Dimensions	9 x 6.5 x 4 inch (22.9 x 16.5 x 10.2 cm)
Instrument Weight	0.92 kg (2.03 lbs) without NiBP and Nomoline capnography
Electrical	
AC power	Input Voltage: 100-240 VAC, 47-63 Hz
Battery power	Internally rechargeable lithium ion battery
I/O Interface	
USB	USB interface
Nurse call	Analog output
Ethernet	Provides network connection to the device using RJ-45 cable
Wireless	Wi-Fi, Bluetooth
Mode of Operation	

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Mode of operation	Continuous operation

5.2. 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 (SpO2) of adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

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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
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Adult	21 years of age and older

Devices with Masimo technology are only indicated for use with Masimo sensors and cables.

The Masimo Rad-97 and Accessories are indicated for the continuous non-invasive monitoring of PVi as a measure of relative variability of the photoplethysmograph (pleth) for adults and pediatrics during no motion conditions in hospitals and hospital-type facilities.

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

5.3. Technological Characteristics

Principle of Operation

The subject of this submission is the addition of the indication for the continuous non-invasive monitoring of Pleth Variability index (PVi) which is a measure of the relative variability of the photo plethysmograph (PPG or pleth) due to respiration. Clinically, the variations in blood pressure and blood volume is used for the monitoring of cardiac output as an indicator of hemodynamic stability, which can be affected by the balance of dynamic factors such as cardiac function, fluid changes, and vascular resistance.

Through the use of the pleth waveform used in SpO2 monitoring, the variations associated with the changes in the stroke volume can also be detected. The ability to detect these changes in blood saturation and pulsatile blood flow is based upon the Beer-Lambert law, which establishes the relationship between the absorption of light to the concentration of the absorption media. The variations in the absorption (Pi) are then used to calculate PVi.

The PVi feature relies on the relationship defined by the Frank-Starling curve along with principles used for pulse oximetry to allow for the continuous and noninvasive indication of fluid responsiveness by

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continuously calculating the detected variability in the pleth waveform associated with a respiration cycle. Following the Frank-Starling curve, the relationship of a high, low, increasing, or decreasing PVi can also be indicative of the relative stability of the stroke volume associated with the amount of ventricular end-diastolic volume or restated as the fluid responsiveness. As many factors such as the patient and procedure may affect the accuracy of the indication of fluid responsiveness, the current submission is for PVi as an indicator of fluid responsiveness for select populations of mechanically ventilated adult patients.

Mechanism of Action for Achieving the Intended Effect

The mechanism of action for the monitoring of PVi does not change as part of this submission. PVi is monitored by application of a Masimo SpO2 sensor to an appropriate application site. The sensor utilizes the same SpO2 wavelengths of light form the sensor to detect differing absorption levels of light. The photodetector provided on the sensor detects the transmitted light and to establish the pleth waveform that is displayed on the monitor. The PVi is calculated continuously to provide an indication of the relative stability of the pleth.

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

The subject device, Masimo Rad-97 with indications for PVi, and the primary predicate device, Masimo Rad-97 (K183697), 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 devices have the same principle of operation

The subject device, Masimo Rad-97 with indications for PVi, and the primary predicate, Masimo Rad-97 (K183697), have the following key differences:

- Subject device includes proposed indication for PVi, where the predicate device did not have an indication associated with this particular calculation.

5.5. Performance Data

Biocompatibility Testing:

There were no new patient contacting parts or materials related to the introduction of indications for the PVi feature. Therefore, no additional biocompatibility testing was not included as part of this submission.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and

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Cleaning

There were no hardware changes related to the introduction of indications for the PVi feature. Therefore, no additional EMC, Electrical Safety, Environmental, Mechanical, and Cleaning tests were not included as part of this submission.

Software Verification and Validation Testing

There were no software changes related to the PVi feature. Therefore, no additional software testing specific to the PVi feature was included as part of this submission.

Wireless and Cybersecurity Testing

There were no wireless or interconnectivity changes related to the PVi feature, There, no additional wireless or cybersecurity testing was included as part of this submission.

Human Factors Usability Testing

There were no change made to the software or hardware user interfaces related to the PVi feature. Thus, no additional human factors or usability testing was included as part of this submission.

Non-clinical Testing

There were no changes to the way the PVi feature is calculated as part of this submission. Therefore, no additional performance bench testing was included as part of this submission.

Clinical Testing

To support the acceptability of the PVi feature for its updated indications, a comparison of the performance in the determination of fluid responsiveness using a fluid bolus infusion and monitoring the cardiac output response was conducted. To support the indication, 30 published studies were provided. Highlighted were 6 studies, which included a combined 182 subjects undergoing surgeries, where PVi was monitored for fluid responsiveness using volume expansion changes (fluid bolus infusions) on mechanically ventilated adults. The test results supported the ability of PVi to provide an indication of fluid responsiveness in those studied mechanically ventilated adult patients.

Table 5.5-1 Summary of Comparison

Study Number	Area Under the Curve (AUC)
1	0.785
2	0.95
3	0.97
4	0.82
5	0.74
6	0.934

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5.6. Conclusion

The data provided as part of this submission for the subject device supports the substantially equivalence to the predicate device.