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

Re: K182887
Trade/Device Name: Masimo Rad-67 Pulse CO-Oximeter and Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: February 19, 2019
Received: February 21, 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,

Todd D. Courtney
-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)*
K182887

Device Name
Masimo Rad-67™ Pulse CO-Oximeter

Indications for Use *(Describe)*
Indications For Use:

Masimo Rad-67™ Pulse CO-Oximeter

The Masimo Rad-67™ Pulse CO-Oximeter and Accessories are intended for use in clinical and non-clinical settings.

The Masimo Rad-67™ Pulse CO-Oximeter and Accessories are indicated for non-invasive spot-check monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients who are well or poorly perfused during both motion and no motion conditions.

The Masimo Rad-67™ Pulse CO-Oximeter and Accessories are indicated for non-invasive spot-check monitoring of total hemoglobin concentration (SpHb®) for adult patients.

rainbow DCI-mini sensor

The rainbow DCI-mini sensor is intended for use in clinical and non-clinical settings.

The rainbow DCI-mini sensor is indicated for non-invasive spot-check monitoring and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients who are well or poorly perfused during both motion and no motion conditions.

The rainbow DCI-mini sensor is indicated for non-invasive spot-check monitoring of total hemoglobin concentration (SpHb®) for adult patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5. 510(k) Summary

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 11th 2018
Official Correspondent	Sindura Penubarthi Regulatory Affairs Manager Masimo Corporation Phone: (949)297-7541 SPenubarthi@Masimo.com
Trade Name:	Masimo Rad-67™ Pulse CO- Oximeter and Accessories
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/DQA
Establishment Registration Number:	2031172
Reason for Premarket Notification:	New Device – Masimo Rad-67™ Pulse CO-Oximeter and Accessories
Predicate Device:	K091057- Masimo Rainbow SET Pronto Pulse CO-Oximeter
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

5.1 Device Description

The Masimo Rad-67™ Pulse CO-Oximeter is a handheld device that includes the Masimo Rainbow SET measurements.

The Rad-67™ has the same measurement technology and intended use as the cleared predicate, Pronto (K091057). The Rad-67™ includes Masimo Rainbow SET measurement technology, which enables the Rad-67™ to provide noninvasive spot-check monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), Perfusion Index (Pi) and total hemoglobin concentration (SpHb®). The Rad-67™ can communicate through a wired or wireless connection to transfer data to external applications and devices.

The rainbow DCI-mini sensor, compatible accessory to the Rad-67™, is a reusable sensor that is compatible with Masimo rainbow SET technology and is intended for spot-check monitoring of

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

functional oxygen saturation (SpO_2), pulse rate (PR) and total hemoglobin (SpHb®). The rainbow DCI-mini sensor is indicated for adult, pediatric and infant populations≥ 3kg for SpO_2 and PR. The rainbow DCI-mini sensor is indicated for adult populations for SpHb®. The rainbow DCI-mini sensor measurement technology is the same as the predicate (rainbow DCI sensor cleared under K080238), except that the rainbow DCI-mini sensor has been designed to be smaller to accommodate a smaller application sites such as the great toe or thumb (for the infant population) and the finger (for adults and pediatric).

5.2 Significant Physical and Performance Characteristics of the Device

The table below provides the specifications for the Rad-67™.

Table 5.2 Rad-67™ Pulse CO-Oximeter Specifications	
FEATURE	Specification
Display	
Display type	Touchscreen, Color LCD (Backlit Active Matrix TFT LCD)
Measurement range	Functional Oxygen Saturation (SpO2):0-100%
	Pulse Rate (PR): 0-240 beats per minute (bpm)
	Perfusion Index (Pi): 0.00-20%
	Pleth Variability Index (PVi): 0 to 100%
	Total Hemoglobin (SpHb): 0 to 25g/dL; 0 to 250 g/L; 0 to 15.5mmol/L
Display resolution	SpO2:1%
	PR:1bpm
	SpHb: 0.1, 0.5, 1 g/dL; 1g/L; 0.1, 0.5, 1 mmol/L
Accuracy (A_{RMS})	Masimo rainbow SET Parameters
SpO2, no motion (70-100%)	2%, adults/pediatrics/infants
SpO2, motion (70-100%)	3%, adults/pediatrics/infants
SpO2, low perfusion (70-100%)	2%, adults/pediatrics/infants
Pulse rate, no motion (25-240 bpm)	3bpm, adults/pediatrics/infants
Pulse rate, motion (25-240 bpm)	5bpm, adults/pediatrics/infants
Pulse rate, low perfusion (25-240 bpm)	3 bpm, adults/pediatrics/infants
SpHb Limits of agreement (LOA) over a range of 8-17 g/dL	-1.82 to 2.04 g/dL
Mechanical	
Dimensions	19.43 cm x 8.2 cm x 2.36 cm (7.6” x 3.2” x 0.9”)
Weight	0.37 kg. (0.81lbs)
Environmental	
Operating Temperature	0 to 35 ºC (32 to 95 ºF)
Storage/Transport Temperature	-20˚C to 45˚C (-4˚F to 113˚F)
Operating Humidity	10% to 95%, non-condensing
Storage/Transport Humidity	10% to 95%, non-condensing
Operating Atmospheric Pressure	540 mbar to 1060 mbar (540 hPa to 1060hPa)
Electrical	
AC power (power supply) requirements	100-240Vac, 50/60 Hz, 0.5A
Power consumption	<15W
Safety Standard Compliance	IEC 60601-1:2005

MASIMO CORPORATION
52 Discovery
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Section 5. 510(k) Summary

Table 5.2 Rad-67™ Pulse CO-Oximeter Specifications	
FEATURE	Specification
	IEC 60601-1-2:2007 ISO 80601-2-61:2011
Type of Protection	Class II (AC Power); internally powered (Battery power)
Degree of protection	Defibrillation proof, BF applied part
Protection against liquid ingress	IPX4
Mode of Operation per IEC 60601-1	Continuous operation

5.3 Intended Use/Indications for Use

Masimo Rad-67™ Pulse CO-Oximeter

The Masimo Rad-67™ Pulse CO-Oximeter and Accessories are intended for use in clinical and non-clinical settings.

The Masimo Rad-67™ Pulse CO-Oximeter and Accessories are indicated for non-invasive spot-check monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients who are well or poorly perfused during both motion and no motion conditions.

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rainbow DCI-mini sensor

The rainbow DCI-mini sensor is intended for use in clinical and non-clinical settings.

The rainbow DCI-mini sensor is indicated for non-invasive spot-check monitoring and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients who are well or poorly perfused during both motion and no motion conditions.

The rainbow DCI-mini sensor is indicated for non-invasive spot-check monitoring of total hemoglobin concentration (SpHb®) for adult patients.

5.4 Technological Characteristics

5.1.1. Principle of Operation – Pulse CO-Oximeter (Masimo SET and Masimo rainbow SET)

Pulse CO-Oximetry is governed by the following principles based upon the Beer-Lambert Law, which relates the attenuation of light to the properties of the material it passes through:

- Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood), and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Section 5. 510(k) Summary

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

The Masimo rainbow SET technology uses a multi-wavelength sensor to detect the physiological signals required for the indicated parameters based on light absorption of various constituents in blood such as oxy- and deoxy- hemoglobin. The signal collected are processed to provide the measurements.

5.1.2. Mechanism of Action for Achieving the Intended Effect

The mechanism for action for the Rad-67 is equivalent to the predicate in that it operates by connecting a multiple wavelength sensor and applying the sensor patient applied part to the measurement site. Once the sensor is applied to the measurement site, similar to the predicate device, the clinician can initiate the measurement through subject device interface. Once the measurement is initiated, physiological signals are detected via the patient applied part and sent to the subject device for processing to obtain a measurement. The measurement is then relayed to the clinician through the subject device's display.

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

The subject device, Rad-67™, and the predicate device, Pronto, have the following key similarities:

- both have substantially the same indications for use,
- both have the same principle of operation, mechanism of action, and performance specifications for Masimo rainbow SET technologies,
- both have substantially the same intended environment (e.g. clinical and non-clinical settings),

The subject device, Rad-67™, and the predicate device, Pronto, have the following key differences:

- the subject device includes modifications to the device software,
- the subject device includes a rechargeable lithium ion battery, whereas the predicate device uses non-rechargeable alkaline battery,
- the subject device includes touchscreen interface instead of membrane switch pad,
- the subject device includes wireless capabilities, whereas the predicate does not include wireless connectivity,
- the subject device includes a different sensor port connector

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Section 5. 510(k) Summary

5.5 Non-clinical Testing

The following tests, as applicable, were performed for the qualification of the subject Rad-67™ device and rainbow DCI-mini sensor in accordance with the requirements of the design control regulations and established quality assurance processes to demonstrate substantial equivalence with its predicates:

- Electrical safety testing per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Usability testing per FDA Human Factors and Usability Draft Guidance
- Software verification, including integration testing with host monitors, per FDA Software Guidance
- Biocompatibility testing per ISO-10993 (rainbow DCI-mini)
- Mechanical testing per ISTA 2A and MIL-STD 810E
- Environmental testing per IEC 60601-1

5.6 Clinical Testing

Masimo performed clinical studies on Rad-67™ and rainbow DCI-mini sensors in accordance with ISO-80601-2-61.

To establish substantial equivalence, clinical validation testing of the SpHb and SpO2 performance specification was conducted and included as part of this submission. The clinical studies for the Rad-67™ including the rainbow DCI-mini sensor supported the substantial equivalence to the predicate. The summary of the testing is provided below in Table 5.6.

Table 5.6 Clinical Validation studies

<table>
<tr><th>Objective</th><th>Test results</th></tr>
<tr><td>Clinical Validation Study (SpHb)
The clinical accuracy of the SpHb performance was validated to obtain a 95% Limits of Agreement (LOA) specification over the range of 8-17g/dL as compared to tHb values determined by a HiCN reference method</td><td>
<table>
<tr><th>Reference Method</th><th># Subjects</th><th>95% LOA Accuracy[g/dL]</th></tr>
<tr><td>HiCN</td><td>317</td><td>-1.82 to 2.04</td></tr>
</table>
</td></tr>
<tr><td>Clinical Validation Study (SpO_2) (No motion)
The clinical accuracy of the SpO_2 performance specification for no motion conditions was validated to meet the 2% Arms specification, the same as the predicate.</td><td>
<table>
<tr><th colspan="4">SpO_2 A_{rms} for no motion (70-100%)</th></tr>
<tr><td></td><td>Bias</td><td>Prec</td><td>RMS</td></tr>
<tr><td>No motion</td><td>0.05</td><td>1.63</td><td>1.63</td></tr>
</table>
</td></tr>
<tr><td>Clinical Validation Study (SpO_2)
The clinical accuracy of the SpO_2 performance specification for motion conditions was validated to meet the 2% Arms specification, the same as the predicate</td><td>
<table>
<tr><th colspan="4">SpO_2 A_{rms} for motion</th></tr>
<tr><td></td><td>Bias</td><td>Prec</td><td>RMS</td></tr>
<tr><td>motion</td><td>-0.49</td><td>1.92</td><td>1.98</td></tr>
</table>
</td></tr>
</table>

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Irvine, CA 92618

Section 5. 510(k) Summary

5.6.1 Masimo performed the SpHb clinical validation testing of the SpHb performance using 317 adult subjects in the range of 8-17 g/dL. The 95% LOA was calculated for SpHb to be -1.82 to 2.04 g/dL over a specification range of 8-17 g/dL.

5.6.2 Masimo performed the clinical validation testing of the SpO2 performance under no motion on healthy, adult volunteers in the range of 70% to 100%. The A_{RMS} for SpO2 under no motion was found to be 1.6% over the range of 70-100%.

5.6.3 Masimo performed the clinical validation testing of the SpO2 performance under motion on healthy, adult volunteers in the range of 70% to 100%. The A_{RMS} for SpO2 under motion was found to be 1.9% over the range of 70-100%.

5.7 Conclusion

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