September 24, 2020

Masimo Corporation
Katelynn Kirby
Regulatory Affairs Specialist III
52 Discovery
Irvine, California 92618

Re: K201770
Trade/Device Name: Masimo Rad-G Pulse Oximeter and Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, DPZ, BZQ
Dated: September 2, 2020
Received: September 3, 2020

Dear Katelynn Kirby:

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

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)*
K201770

Device Name
Masimo Rad-G Pulse Oximeter and Accessories

Indications for Use *(Describe)*
The Rad-G Pulse Oximeter and Accessories are intended for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), Pulse Rate (PR), and Pleth Respiration Rate (RRp).

The Rad-G Pulse Oximeter and Accessories are indicated for noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) of adult, pediatric, infant, and neonate patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, transport, and home environments.

The Rad-G Pulse Oximeter and Accessories are indicated for the spot-checking or continuous monitoring of Respiration Rate from the photoplethysmogram (RRp) of adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, transport, and home environments.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	June 26 2020
Contact:	Katelynn Kirby Regulatory Affairs Specialist III Masimo Corporation Phone: (949) 297-7408
Trade Name:	Masimo Rad-G Pulse Oximeter and Accessories
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/DQA
Additional Classification Regulation/Product Code(s):	21 CFR 868.2375, Class II/BZQ
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	New Device
Predicate Device:	Masimo Radical-7 Pulse Co-Oximeter and Accessories (K193242)
Reference Predicate	Masimo MightySat Rx Fingertip Pulse Oximeter (K181956)
Performance Standards	No performance standards for the above device have been promulgated pursuant to Section 514.

The purpose of this premarket notification is to receive authorization to market the Masimo Rad-G and Accessories.

1. Device Description

The Rad-G is a handheld pulse oximeter that provides Masimo SET pulse oximetry and Respiration Rate from the Plethysmograph. The Rad-G is provided with an internal battery and a connection to an external power supply to support continuous monitoring. The technologies supported in the Rad-G are the same as what has been cleared with the Radical-7.

The Rad-G can be used with the following sensors:

Rad-G Reusable Sensor (As part of this submission)
Rad-G YI Sensor (As part of this submission)

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RD SET Disposable sensors (K191059)
RD SET Reusable sensors (K180046)

The following are specifications for the Rad-G Pulse Oximeter:

General Information	
Display	
Display Type	Touchscreen
Technological Characteristics	
Supported Parameters	SpO2, PR, RRp
Calculated or Derived Parameters	PVi
Performance Specification (Arms)	
SpO2, no motion (70-100%)	2% (Adults/Pediatrics/Infants) 3% (Neonates)
SpO2, motion (70-100%)	3% (Adults/Pediatrics/Infants/Neonates)
SpO2, low perfusion (70-100%)	2% (Adults/Pediatrics/Infants) 3% (Neonates)
Pulse rate, no motion (25-240 bpm)	3 bpm
Pulse rate, motion (25-240 bpm)	5 bpm
Pulse rate, low perfusion (25-240 bpm)	3 bpm
Respiration Rate from Pleth (4-70 rpm)	3 rpm Arms, 1 rpm Mean Error (Adults/Pediatrics)
Environmental	
Operating Temperature	0 to 40 ºC (32 to 104 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	7.8 x 2.9 x 1 inch (19.8 x 7.4 x 2.5 cm)
Instrument Weight	0.27 kg (0.59 lbs)
Electrical	
AC Power Supply, External (Input Voltage)	100-240 VAC, 50/60 Hz, 0.6A
Battery power	Internally rechargeable lithium ion battery
I/O Interface	
Wireless	Wi-Fi, Bluetooth
Mode of Operation per IEC 60601-1	
Mode of operation	Continuous

2. Intended Use/ Indications for Use

The Rad-G Pulse Oximeter and Accessories are intended for the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), Pulse Rate (PR), and Pleth Respiration Rate (RRp).

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The Rad-G Pulse Oximeter and Accessories are indicated for noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) of adult, pediatric, infant, and neonate patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, transport, and home environments.

The Rad-G Pulse Oximeter and Accessories are indicated for the spot-checking or continuous monitoring of Respiration Rate from the photoplethysmogram (RRp) of adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, transport, and home environments.

3. Technological Characteristics

Principle of Operation

The Rad-G Pulse Oximeter and Accessories utilize the same principles of operation for functional oxygen saturation of arterial hemoglobin (SpO2), Pulse Rate (PR), and Respiration Rate from the Pleth (RRp) as the Radical-7 previously FDA 510(k) cleared under K193242. The principles of operation of pulse oximetry is based upon the fundamental principle that hemoglobin bound to oxygen (oxyhemoglobin) and hemoglobin unbound to oxygen (deoxyhemoglobin) vary in the absorption of different wavelengths of the light and the absorptions can be used to estimate SpO2 and PR. RRp relies on the principle that the cyclic variations in plethysmograph can be used to establish a respiration rate measurement.

Mechanism of Action for Achieving the Intended Effect

The Rad-G Pulse Oximeter and Accessories, the same as the predicate, provide the intended effect similar to the previously cleared Radical-7 in that it utilizes an optical sensor that is applied to the patient's finger to pass light through the tissue to the photodetector that detects the signal variation resulting from differences in the absorption of light. The signals are then passed to the Rad-G Pulse Oximeter where they are processed to provide the SpO2, PR, and RRp values that are then displayed.

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-G and Accessories, and the predicate device, Masimo Radical-7 and Accessories (K193242), have the following key similarities:

- Both devices utilize the same technology to continuously monitor Masimo SET Technology and support Respiration rate through Plethysmograph (RRp)
- Both devices have the same performance specifications for the parameters
- Both devices utilize a touch screen user interface with a similar graphical user interface layout
- Both devices are provide with internal rechargeable batteries so that they can operate on internal battery or AC power

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The subject device, Masimo Rad-G and Accessories, and the predicate device, Masimo Radical-7 and Accessories (K193242), have the following key differences:

- The subject device includes an indication for spot-checking
- The subject device only provides a smaller subset of monitoring parameters
- The subject device has different environmental specifications, including ingress protection rating
- The subject device has a different physical appearance (e.g. enclosure size and shape)
- The subject device does not require a docking station in order to be powered by AC power

See Table 4.1 for the comparison between the subject device and predicate device.

As compared to the Radical-7, the main modifications are in the added spot-checking indication, physical appearance, ability to connect directly to as external AC/DC power supply versus a docking station, environmental specifications, and the software which was modified to be compatible with the Rad-G hardware and support the simplification of the user interface to limit the number of displayed parameters, as compared to the Radical-7.

The substantial equivalence of the Rad-G to the predicate device, Radical-7, was supported by the same intended use and technological characteristics in providing SpO2, PR, and RRp. To support the indication for spot-checking do not raise different questions of safety and effectiveness, the MightySat (K181956), which is cleared for spot-checking and has similar technological characteristic, was included as a reference predicate. The non-clinical testing supported the other differences related to the software, environmental specifications, AC power source, and physical characteristics do not raise new questions of safety and effectiveness. The testing was found to support the substantial equivalence of the subject device to the predicate.

Table 4.1– Comparison Table

Feature	Subject Device	Radical-7, Predicate device	Comparison
510(k) Number	Pending	K193242	
General Information			
Classification/Product Code	21 CFR 870.2700, Class II/DQA	21 CFR 870.2700, Class II/DQA	Same
Additional Classification/Product Code	21 CFR 868.2375, Class II/BZQ	21 CFR 868.2375, Class II/BZQ 21 CFR 862.3200, Class II/JKS 21 CFR 870.2710, Class II/DPZ	Subject device supports a smaller set of product codes.
Indications for Use	The Rad-G Pulse Oximeter is intended for the	The Radical-7 and Accessories are indicated	Subject device supports a smaller set of monitoring

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	noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), Pulse Rate (PR), and Pleth Respiration Rate (RRp). The Rad-G Pulse Oximeter is indicated for use the noninvasive spot-checking or continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR)of adult, pediatric, infant, and neonate patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, transport, and home environments. The Rad-G Pulse Oximeter is indicated for use the noninvasive spot-checking or continuous monitoring of Respiration Rate from the photoplethysmogram (RRp) of adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, transport, and home environments.	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 Radical-7 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 Radical-7 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 Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of methemoglobin saturation	parameters. Subject device supports both spot-checking and continuous monitoring.

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		(SpMet) of adult, pediatric, and neonatal patients during no motion conditions in hospitals and hospital-type facilities. The Radical-7 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 Radical-7 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 Radical-7 and Accessories are indicated for the continuous non-invasive monitoring of respiratory rate from the Pleth (RRp) for adult and pediatric patients during no motion conditions in hospitals, hospital-type facilities, home environments, and transport within healthcare facilities.	

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Principle of operation	SpO2 and Pulse Rate relies on the principle that hemoglobin at different oxygenation states absorb light differently based upon the wavelength of light. RRp feature relies on the principle subject's respiration rate modulates the photoplethysmogram (i.e. pleth or PPG), derived from the absorption of red/infra-red absorption in SpO2 used in three ways: respiratory induced amplitude variation (RIAV), respiratory induced intensity variation (RIIV), and respiratory sinus arrhythmia (RSA).	SpO2 and Pulse Rate relies on the principle that hemoglobin at different oxygenation states absorb light differently based upon the wavelength of light. RRp feature relies on the principle subject's respiration rate modulates the photoplethysmogram (i.e. pleth or PPG), derived from the absorption of red/infra-red absorption in SpO2 used in three ways: respiratory induced amplitude variation (RIAV), respiratory induced intensity variation (RIIV), and respiratory sinus arrhythmia (RSA).	Same for the supported parameters
Display			
Display Type	Touchscreen	Touchscreen	Same
Alarm			
Alarm Type(s)	Visual, Audible	Visual, Audible	Same
Technological Characteristics			
Display/Indicators			
Supported Parameters	SpO2, PR, PVi, and RRp,	SpO2, PR, PVi, RRp, SpCO, SpMet, SpHb, SpOC, RRa	Subject device supports a smaller set of parameters
Display Range			
SpO2	0-100%	0-100%	Same
Pulse Rate	25-240 bpm	25-240 bpm	Same
Pi	0.02-20%	0.02-20%	Same
PVi	0-100%	0-100%	Same
Respiratory Rate from Pleth	4-70 respirations per minute	4-70 respirations per minute	Same
Performance (Arms)			
SpO2, No Motion (70-100%)	2% (Adults/Pediatrics/Infants) 3% (Neonates)	2% (Adults/Pediatrics/Infants) 3% (Neonates)	Same
SpO2, Motion (70-100%)	3%	3%	Same
SpO2, Low Perfusion	2%	2%	Same

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(70-100%)	(Adults/Pediatrics/Infants) 3% (Neonates)	(Adults/Pediatrics/Infants) 3% (Neonates)	
Pulse Rate, No Motion (25-250 bpm)	3 bpm	3 bpm	Same
Pulse Rate, Motion (25-250 bpm)	5 bpm	5 bpm	Same
Pulse Rate, Low Perfusion (25-250 bpm)	3 bpm	3 bpm	Same
Respiration Rate from Pleth (4-70 rpm)	3 rpm A_{RMS}, 1 rpm Mean Error (Adults/Pediatrics)	3 rpm A_{RMS}, 1 rpm Mean Error (Adults/Pediatrics)	Same
Environmental			
Operating Temperature	0 to 40 ºC (32 to 104 ºF)	0 to 50 ºC (32 to 122 ºF)	Subject device has a lower high temperature specification
Storage Temperature	-20 to 70 ºC (-4 to 158 ºF)	-40 to 70 ºC (-40 to 158 ºF)	Subject device has a higher low temperature specification
Operational/Storage Humidity	10 to 95%, non-condensing	10 to 95%, non-condensing	Same
Operating Atmospheric Pressure	540 mbar to 1,060 mbar (540 hPa to 1060 hPa)	540 mbar to 1,060 mbar (540 hPa to 1060 hPa)	Same
Mechanical			
Dimensions	7.8 x 2.9 x 1 in. (19.8 x 7.4 x 2.5 cm)	8.8 x 3.5 x 1.7 in. (22.3 x 8.9 x 4.3 cm)	Subject device is smaller in size
Weight	0.27 kg (0.59 lbs)	0.59 kg (1.3 lbs.)	Subject device is lighter weight
Electrical			
Supported Power Source	AC Power or Internal Battery	AC Power or Internal Battery	Same
Internal Battery Type	Rechargeable Lithium Ion	Rechargeable Lithium Ion	Same
AC Power Source	External AC Power Supply	External Docking Station (e.g., Root or RDS)	Subject device does not require a docking station.
AC Power	100-240 VAC, 50/60 Hz, 0.6A	100-240 VAC, 47-63 Hz	Similar
I/O Interface			
Network	Wireless (e.g., Wi-Fi, Bluetooth)	Wireless (e.g., Wi-Fi, Bluetooth) and Ethernet	Similar, subject device does not provide an Ethernet connection
Classification per IEC 60601-1			
Mode of Operation	Continuous	Continuous	Same

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5. Performance Data

Biocompatibility Testing:

The Masimo Rad-G is not intended to make direct patient contact. Therefore, biocompatibility testing was not considered necessary.

The accessories which are intended to make contact with the patient were evaluated for biocompatibility. The accessories to be used with the Rad-G are the same as those for the predicate, Radical-7 (K193242), with the exception of the Rad-G reusable and Rad-G YI sensors.

For the Rad-G reusable and Rad-G YI sensors, the patient contacting parts are the same as the previously cleared RD SET version under K193242. The difference between the Rad-G reusable DCI and Rad-G YI sensor is in the device connector which makes them compatible to the Rad-G device.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

Electromagnetic Compatibility, Electrical Safety, Environmental, and Mechanical testing was conducted to support the Masimo Rad-G and Accessories meet its specification and its substantial equivalence. As the Rad-G is not intended to make direct patient contact, cleaning validation was not conducted.

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, which identifies that a failure or latent flaw in the software could directly result in minor to moderate injury to the patient. The test results were found to support the substantial equivalence of the subject device.

Human Factors Usability Testing

As the subject device and the predicate provide similar user interface, the previous human factors testing conducted on the predicate device was considered to support the acceptability of the human factors and usability risks of the subject device. The acceptability of the human factors and usability risks took into account the FDA Guidance, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design*, dated February 3, 2016.

Non-clinical Performance Testing

As the subject device utilizes the same monitoring technologies as the predicate (K193242), non-clinical performance bench testing was performed to ensure the successful integration of the monitoring technologies and electrical sensor connection. The test results were found to support the substantial equivalence of the subject device.

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Clinical Testing

As the subject device utilizes the same monitoring technologies as the predicate (K193242), additional clinical testing was not deemed necessary to support the substantial equivalence.

6. Conclusion

The subject device and the predicate device have the same intended use, and the difference in technological features do not raise different questions of safety and effectiveness. The data provided supports the substantial equivalence of the Masimo Rad-G and Accessories to the proposed predicate device.