# 510(k) SUMMARY

K092838

OCT 1 5 2009

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| **Submitted by:** | Masimo Corporation<br>40 Parker<br>Irvine, CA 92618<br>(949) 297-7000<br>FAX (949) 297-7001 |
| **Company Contact:** | Marguerite Thomlinson, Manager of Regulatory Affairs |
| **Date Summary Prepared:** | September 14, 2009 |
| **Trade Name** | Masimo SET® Rad-8 Pulse Oximeter and Accessories, Model Rad-8 |
| **Common Name** | Pulse Oximeter |
| **Classification Name** | Oximeter (74DQA) (870.2700) |
| **Substantially Equivalent Devices** | Masimo SET® Rad 8 Pulse Oximeter<br>510(k) Number – K053269 |

**Device Description**

The Masimo SET® Rad-8 Pulse Oximeter and Accessories (Rad 8) have the following features and benefits:

- Clinically proven Masimo SET technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- $SpO_2$, pulse rate, alarm, and perfusion index displays
- Signal IQ™ for signal identification and quality indication
- Lightweight, convenient handheld design
- Audible alarm for sensor-off and low battery
- Alarms for Hi/Low saturation and pulse rate
- Trauma and FastSat™
- Three sensitivity levels – Max, Normal and APOD™
- Adjustable alarm volume
- Adjustable averaging 2 to 16 seconds
- Trend data storage and output
- Two models: Horizontal or Vertical position

The Rad 8 in this filing is substantially equivalent to the predicate device (K053269). The reason for this filing is to revise the upper limit of the pulse rate accuracy range.

**Predicate Device**

The predicate device used in this filing is the Masimo SET® Rad 8 Pulse Oximeter, 510(k) No. K053269.

# 510(k) SUMMARY

### Indications For Use/ Intended Use

The Masimo SET® Rad-8 Pulse Oximeter and Accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin ($SpO_2$) and pulse rate (measured by an $SpO_2$ sensor). The Masimo SET® Rad-8 Pulse Oximeter and Accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, for patients who are well or poorly perfused, in hospitals, hospital-type facilities, mobile, and home environments.

### Technology Comparison

The Rad 8 in this filing is substantially equivalent in design, principles of operation, materials, and performance to predicate device (K053269). The only difference is the change of the upper limit of the pulse rate range from 240 to 300 beats per minute.

Similar to the predicate, the Rad 8 in this filing is designed, configured, and manufactured for full compatibility with Masimo sensors.

### Specifications

The following are the device specifications for the Rad 8:

| FEATURES | SPECIFICATIONS |
|---|---|
| **Display Range** | |
| | Saturation ($SpO_2$): 1% - 100%<br>Pulse Rate (bpm): 25 – 480 bpm<br>Perfusion Index: 0.02% - 20% |
| **Accuracy** | See footnotes 1, 2, 3, 4 and 5 |
| $SpO_2$, No Motion Conditions | Pediatrics, Infants, Neonates: 60 - 80% ± 4% |
| | Adults, Pediatrics: 70% - 100% ± 2%<br>Neonates: 70% - 100% ± 3%<br>Adults, Pediatrics, Neonates: 0% - 69% unspecified |
| $SpO_2$, Motion Conditions | Adults, Pediatrics, Neonates: 70% - 100% ± 3%<br>Adults, Pediatrics, Neonates: 0% - 69% unspecified |
| $SpO_2$, Low Perfusion | Adults, Pediatrics, Neonates: 70% - 100% ± 2%<br>Adults, Pediatrics, Neonates: 0% - 69% unspecified |
| Pulse Rate, No Motion Conditions | Adults, Pediatrics, Neonates: 25 - 300 ± 3 bpm |
| Pulse Rate, Motion Conditions | Adults, Pediatrics, Neonates: 25 - 300 ± 5 bpm |
| Pulse Rate, Low Perfusion | Adults, Pediatrics, Neonates: 25 - 300 ± 3 bpm |
| **General** | |
| Resolution | $SpO_2$: 1%<br>Pulse Rate: 1 bpm |
| Measurements | Low Signal IQ<br>Perfusion Index (PI) |
| Interfering Substances | • Elevated levels of Methemoglobin (MetHb) may lead to inaccurate $SpO_2$ measurements<br>• Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate $SpO_2$ measurements.<br>• Severe anemia may cause erroneous $SpO_2$ readings.<br>• Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.<br>• Elevated levels of total bilirubin may lead to inaccurate $SpO_2$, readings |

# 510(k) SUMMARY

| FEATURES | SPECIFICATIONS |
|---|---|
| **Electrical** | |
| Power (AC) | Voltage Input Range: 100-240 Vac, 47-63 Hz<br>Max. AC Power Consumption: 20 VA |
| Power (battery) | One rechargeable sealed lead acid battery<br>Operating time: up to 7 hours<br>Charging time: approximately 8 hours |
| Circuitry | Microprocessor controlled |
| Firmware | Masimo SET technology, MS-2000 Series Technology Board |
| **Mechanical** | |
| Material | Polycarbonate/ABS Blend |
| **Environmental** | |
| Operating Temperature | 41°F to +104°F (5°C to +40°C) |
| Storage Temperature | -40°F to +158°F (-40°C to +70°C) |
| Relative Humidity | 5% to 95% noncondensing |
| Operating Altitude | Operating Altitude: 500 mbar to 1,060 mbar pressure; -1,000 ft to 18,000 ft (-304 m to 5,486m) |
| **Mode & Sensitivity** | |
| Averaging Mode | General: 2, 4, 6, 8, 10, 12 and 16 seconds<br>FastSat |
| Sensitivity | APOD, Normal, Maximum |
| **Alarms** | |
| Out of Limits | High and low alarms for $SpO_2$ and Pulse Rate |
| Sensor Condition | No Sensor, Sensor Off |
| Battery | Low battery |
| System | System failure |
| **Display and Indicators** | |
| Data Display | %$SpO_2$<br>Pulse rate<br>Alarm status<br>Status messages<br>Signal IQ<br>Perfusion index<br>FastSat<br>Trauma<br>Battery status<br>Sensor status |
| Display Type | LED |
| **Output Interface** | |
| Serial Output Port | RS-232 Connector |
| Open/Close Switch | Nurse Call |
| **Compliance** | |
| EMC Compliance | EN 60601-1-2, Class B |
| Electrical Safety | IEC 60601-1,<br>UL 60601-1 |
| Type of Protection (AC power) | Class 1 |
| Type of Protection (battery power) | Internally Powered |
| Degree of Protection-Patient Cable | Type BF Defib Proof-Applied Part |
| Enclosed Degree of Ingress Protection from Solids/ Liquids | IPX1 |
| Mode of Operation | Continuous |

# 510(k) SUMMARY

Footnotes:

[1] The Masimo SET Technology with LNOP•Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% $SpO_2$ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses approximately 68% of the population.

[2] The Masimo SET Technology with LNOP Blue sensors has been validated for no motion accuracy in human blood studies in the range of 60 - 100% on neonates, infants and pediatric patients with congenital cyanotic cardiac lesions.

[3] The Masimo SET Technology with LNOP-Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70 - 100% $SpO_2$ against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses approximately 68% of the population.

[4] The Masimo SET Technology with LNOP-Neo and Neo Pt sensors for neonatal motion accuracy is based on human blood studies for adults (see Notes 1 and 2 above), with added 1% to adult accuracy specifications.

[5] The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses approximately 68% of the population.

**Test Summary**

The Rad 8 complies with the voluntary standards as detailed in this submission. The following quality assurance measures were applied to the development of the Rad 8:

- Risk Analysis
- Design Reviews
- Biocompatibility Testing
- Performance Testing
- Safety Testing
- Environmental Testing
- Clinical Testing

**Conclusions**

The information in this 510(k) submission demonstrates that the Masimo SET® Rad 8 Pulse Oximeter and Accessories are substantially equivalent to the predicate device, with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Ms. Marguerite Thomlinson
Manager of Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

OCT 15 2009

Re: K092838
Trade/Device Name: Masimo SET® Rad-8 Pulse Oximeter and Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DPZ
Dated: September 14, 2009
Received: September 15, 2009

Dear Ms. Thomlinson:

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. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** _____

**Device Name:** Masimo SET® Rad-8 Pulse Oximeter and Accessories

**Indications For Use:**

The Masimo SET® Rad-8 Pulse Oximeter and Accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin ($SpO_2$) and pulse rate (measured by an $SpO_2$ sensor). The Masimo SET® Rad-8 Pulse Oximeter and Accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, for patients who are well or poorly perfused, in hospitals, hospital-type facilities, mobile, and home environments.

**Prescription Use** _____X_____ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109 Subpart D) (Per 21 CFR 801.109 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092838