510(k) SUMMARY

K053269

DEC 2 1 2005

Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 (949) 297-7000 FAX (949) 297-7001
Company Contact:	James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance
Date Summary Prepared:	November 18, 2005
Trade Name	Masimo SET® Rad-8 Pulse Oximeter, Model Rad-8, Kestrel
Common Name	Pulse Oximeter
Classification Name	Oximeter (74DQA) (870.2700)
Substantially Equivalent Devices	Masimo SET® Radical Pulse Oximeter with SatShare™ and the LNOP® series of Sensors and Cables 510(k) Number – K031330 Masimo SET® Rad-5 Pulse Oximeter 510(k) Number – K033296

Device Description

The Masimo SET® Rad-8 Pulse Oximeter has 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 Hi/Low 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

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Intended use

The Masimo SET® Rad-8 pulse oximeter is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Indications For Use:

The Masimo SET® Rad-8 pulse oximeter is 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 is indicated for use with adult, pediatric, and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Principles of Operation:

The principles of operation of the Masimo SET® Rad-8 pulse oximeter are that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography), and that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by the blood is related to hemoglobin oxygen saturation. The Masimo SET® Rad-8 pulse oximeter decomposes the red and infrared pulsatile absorbance signal into an arterial signal plus a noise component and calculates the ratio of the arterial signals without noise. The ratio of the two arterial pulse-added absorbance signals and its value is used to find the SpO_2 saturation in an empirically derived equation in the Masimo SET® Rad-8 software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia states during motion and non-motion conditions.

Method of Operation

The Masimo SET® Rad-8 pulse oximeter is turned on. An oximetry sensor is attached to a patient's finger and one end of a patient cable is connected to the sensor and the other end connected to the Rad-8 pulse oximeter.

The monitor will begin continuously displaying the patient's pulse rate, and SpO_2 value. The practitioner can adjust the high and low alarm limits to their desired value, if required. The practitioner can then use the information that is continuously displayed on the monitor, and hear if an alarm limit is reached, to help assess the condition of the patient and as an aide in determining if any intervention is required by the practitioner.

Once the practitioner determines the patient no longer requires monitoring, the cable is disconnected from the sensor, the oximetry sensor is removed (and disposed of if it is a single use device), and the power to the monitor is turned off.

Power Source

The Masimo SET® Rad-8 pulse oximeter is powered either with a voltage input of 90-240 VAC, 47 - 63 Hz. The detachable portable monitor operates on a rechargeable battery with and operating time of 6 hours*.

Specifications and Operating Ranges

Range	
Saturation (% SpO_2)	1% - 100%
Pulse Rate (bpm)	25 - 240
Perfusion	0.02% - 20%

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Accuracy

Saturation (% SpO_2) - During No Motion Conditions[1]

Adults, Pediatrics	70% - 100% ± 2 digits
	0% - 69% unspecified
Neonates	70% - 100% ± 3 digits
	0% - 69% unspecified

Saturation (% SpO_2) - During Motion Conditions[2,3]

Adults, Pediatrics[2]	70% - 100% ± 3 digits
	0% - 69% unspecified
Neonates[3]	70% - 100% ± 3 digits
	0% - 69% unspecified

Pulse Rate (bpm) - During No Motion Conditions[1]

Adults, Pediatric, Neonates	25 to 240 ± 3 digits

Pulse Rate (bpm) - During Motion Conditions[2,3]

Adults, Pediatric, Neonates	25 to 240 ± 5 digits

Resolution

Saturation (% SpO_2)	1%
Pulse Rate (bpm)	1

Low Perfusion Performance[4]

> 0.02% Pulse Amplitude	Saturation (% SpO_2) ± 2 digits
and % Transmission > 5%	Pulse Rate ± 3 digits

Interfering Substances

Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

Power

Voltage Input Range	90-240 Vac, 47-63 Hz
Maximum AC Power Consumption:	15 VA

Fuses

0.75 A, Time Delay, 250V

Isolation

Chassis Leakage Current	Less than 100 µAmp
Ground resistance	Less than 1.0 Ω

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	500 mbar to 1,060 mbar pressure
	-1,000 ft to 18,000 ft (-304 m to 5,486m)

Circuitry

Microprocessor controlled
Automatic self-test of oximeter when powered on
Automatic setting of default parameters
Automatic alarm messages

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Trend data output of SpO2, pulse rate

Display

Type	LED, 7-segment
Data Displayed	Pulse rate, SpO2 %, alarm status, alarm silenced status, Perfusion Index Bar, Signal IQ Bar, battery status, APOD, Normal, FastSat, Trauma

Audio Indicators

Adjustable volume audible pulse: OFF and 33% to 100% in 3 steps
Adjustable volume audible alarm tone: levels and 33% to 100% in 3 steps
Alarm silence (120 seconds); all mute (continuous silence)
Pulse rate out-of-limits alarm
SpO_2 level out-of limits alarm
Sensor condition alarms
System failure and battery low alarms

Physical Characteristics

Dimension	8.2" x 6.0" x 3.0" (20.8 cm x 15.2 cm x 7.6 cm)
Weight	32oz. (0.908 kg)

Modes

Averaging mode:	2, 4, 6, 8, 10, 12, and 16 seconds
Sensitivity	Normal, APOD, and Max

[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 68% of the population.

[2] 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 68% of the population.

[3] 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.

[4] 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 68% of the population.

[5] This represents approximately run time at lowest indicator brightness and pulse tone turned off, using new, fully charged battery.

Environmental Testing

Applicable environmental testing per the Reviewers Guidance for Premarket Submissions - November 1993, i.e. electrical, mechanical and environmental were performed and all tests passed.

Nonclinical tests performed that support a determination of substantial equivalence.

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The Masimo SET® Rad-8 Pulse Oximeter was subjected to bench testing using a simulator that determined the performance accuracy of the instruments against the simulator under the range of saturation and pulse rates that both devices specify.

The results of the bench testing showed that the Masimo SET® Rad-8 Pulse Oximeter returned the same saturation accuracy values within ± 2 digits and pulse rate values within ± 3 digits when compared to the simulators used.

Clinical tests performed that support a determination of substantial equivalence.

Clinical studies were performed using the Masimo SET® technology on healthy adult volunteer subjects during no motion and motion conditions who were subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were performed using the Masimo SET® technology on healthy adult volunteer subjects who were subjected to low perfusion conditions and to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were conducted following regulations under Title 21 of the Code of Federal Regulations (21CFR), Part 812 - Investigational Device Exemptions, Part 50 - Protection of Human Subjects and Part 56 - Institutional Review Boards.

The results from the clinical studies show that the Masimo SET® technology saturation accuracy values for adults and pediatrics within ± 2 digits during no motion conditions and ± 3 digits during motion conditions when compared to the CO-Oximeter and the pulse rate accuracy values within ± 3 digits during no motion conditions and ± 5 digits during motion conditions when compared to the ECG.

Conclusions

The results of the **environmetal testing** demonstrated that the Masimo SET® Rad-8 Pulse Oximeter **met** the requirements of Reviewers Guidance for Premarket Submissions - November 1993.

The results of the **bench testing** demonstrates that the Masimo SET® Rad-8 Pulse Oximeter **met** its performance requirements.

The results of the **clinical testing** demonstrates that the Masimo SET® technology **meets** its performance requirements during no motion and motion conditions and low perfusion conditions.

The **non-clinical and clinical testing** performed demonstrates that the Masimo SET® Rad-8 Pulse Oximeter is safe, effective, and performs as well as the predicate device, Masimo SET® Radical Pulse Oximeter with SatShare™ and the LNOP® series of Sensors and Cables and Masimo SET® Rad-5 Pulse Oximeter.

OCC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2005

Mr. Jim Cronin
Vice President, Regulatory Affairs/Quality Assurance
Masimo Corporation
40 Parker
Irvine, California 92618

Re: K053269
Trade/Device Name: Masimo SET® Rad-8 Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 22, 2005
Received: November 23, 2005

Dear Mr. Cronin:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): _____

Device Name: Masimo SET® Rad-8 Pulse Oximeter

Indications For Use:

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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