510(k) SUMMARY

MASIMO®
40 Parker
Irvine, CA 92618
Tel: 949-297-7000
Fax: 949-297-7001

K053477

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Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 (714) 297-7000 FAX (714) 297-7001
Company Contact:	James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance
Date Summary Prepared:	December 13, 2005
Trade Name	Masimo Rainbow SET® Rad-57 cm and m Pulse CO-Oximeters and accessories
Common Name	Pulse Oximeter and Sensor
Classification Name	Oximeter (74DQA) Transducer and Electrode Cable (including connector) (74DSA) Carbon monoxide test system (JKS)(862.3220)
Substantially Equivalent Devices	Masimo SET Rad-57 Pulse CO-Oximeter and accessories 510(k) Number K042536 Radiometer America, Inc OSM3 Hemoximeter 510(k) Number – K853990

Description of Masimo Rainbow SET® Rad-57 cm and m Pulse CO-Oximeters

The Rad-57 cm and m Handheld Pulse CO-Oximetesr with Rainbow technology are noninvasive, arterial oxygen saturation and pulse rate monitor that also measure Carboxyhemoglobin and/or Methemoglobin. The Rad-57 features a multicolored LED display that continuously displays numeric values for SpO2 and pulse rate, a Low Signal IQ Indicator (Low SIQ) indicator, LED indicator bars for Perfusion Index (PI) and Carboxyhemoglobin saturation (%SpCO) and/or Methemoglobin saturation (%SpMet), alarm status, alarm silence, battery life and SpCO/SpMet sensor connected. The Masimo SET Rad-57 cm and m Pulse CO-Oximeters are intended to be used with Masimo's LNOP and LNCS series of oximetery sensors and patient cables and Masimo's Rainbow SpCO/SpMet sensors and Rainbow cables.

Features and Benefits

- Clinically proven Masimo SET™ technology performance
- Applicable for use on neonate, infant, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO2, pulse rate, alarm, Perfusion Index, % SpCO and/or SpMet displays
- Low Signal IQ (SIQ) indicator
- Lightweight, convenient handheld design
- Up to 8 hours continuous use on 4 "AA" alkaline batteries
- Visual battery life indicator

Audible Alarm for sensor-off and low battery
Alarms for Hi/Low saturation and Hi/Low pulse rate, SpCO, SpMet
FastSat™ (for SpO_2 measurement)
Three sensitivity levels - Max, Normal and APOD™ (for SpO_2 measurement)
72 hours of trending memory
Adjustable alarm volume
Adjustable averaging 2 to 16 seconds

Intended use

The Masimo SET® Rad-57 cm and m Pulse CO-Oximeters and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), carboxyhemoglobin, and/or methemoglobin saturation (measured by an SpCO/SpMet sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Indications for use

The Masimo SET® Rad-57 cm and m Pulse CO-Oximeters 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) and carboxyhemoglobin and methemoglobin saturation or methemoglobin (measured by an SpCO/SpMet sensor). The Masimo SET® Rad-57 cm and m Pulse CO-Oximeters and accessories are indicated for use with 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.

Principles of Operation

SpO2 General Description
Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults, and the hand or foot for neonates. The sensor connects to the pulse oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in two ways: 1) as a percent value for arterial oxygen saturation (SpO2), and 2) as a pulse rate (PR).

SpCO And SpMet General Description
Pulse CO-oximetry is a continuous and non-invasive method of measuring the levels of carbon monoxide concentration (SpCO) and oxidized hemoglobin concentration (SpMet) in arterial blood. It relies on the same principles of pulse oximetry to make its SpCO/SpMet measurements. The measurements are taken by placing a sensor on a patient, usually on the fingertip for adults. The sensor connects directly to the pulse CO-oximetry instrument or with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpCO and the SpMet. The Rad-57 cm is a combined SpO2, SpCO, and SpMet monitor with the same setup as that of a pulse oximeter and can display percentage values for SpCO and SpMet as well as SpO2 and pulse rate.

Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), and methemoglobin (blood with oxidized hemoglobin content) species differ in their absorption of visible and infrared light.
2. The amount of arterial blood in tissue changes with your pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

The Rad-57 cm handheld Pulse CO-Oximeter uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, and blood with oxidized hemoglobin content. Signal data is obtained by passing various visible and infrared lights (LED's, 400 to 1000nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle.

The photodetector receives the light, converts it into an electronic signal and sends it to the Rad-57 cm for calculation.

Once the Rad-57 cm receives the signal from the sensor, it utilizes Masimo SET signal extraction technology to calculate the patient's functional oxygen saturation, fractional concentrations of carboxyhemoglobin and methemoglobin, and pulse rate. The SpCO and the SpMet measurements rely on multiwavelength calibration equations to estimate the percentages of carboxyhemoglobin and methemoglobin in arterial blood.

Method of Operation

The Masimo Rainbow SET® Rad-57 cm or m Pulse CO-Oximeter is turned on. An oximetery 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-57 cm or m Pulse CO-Oximeter.

The monitor will begin continuously displaying the patient's pulse rate, and SpO_2 value. The practitioner can then use the information that is continuously displayed on the monitor 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 Rainbow SET® Rad-57 cm and m Pulse CO-Oximeters are powered by 4 AA batteries with an operating time of 8 hours[6].

Specifications and Operating Ranges

Range	
Oxygen Saturation (% SpO_2)	1% - 100%
Carboxyhemoglobin Saturation (% SpCO)	1-99%
Methemoglobin Saturation (% SpMet)	1-99.9%
Pulse Rate (bpm)	25 – 240
Perfusion	0.02% - 20%
Accuracy	
Oxygen 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
Oxygen 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
Carboxyhemoglobin Saturation (% SpCO)[4]	0% - 40% ± 3 digits
Methemoglobin Saturation (% SpMet)[4]	0% - 15% ± 1 digits
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
Low Perfusion Performance[4]	
> 0.02% Pulse Amplitude	Oxygen Saturation (% SpO_2) ± 2 digits
and % Transmission > 5%	Pulse Rate ± 3 digits

Resolution

Oxygen Saturation (% SpO_2)	1%
Carboxyhemoglobin Saturation (% SpCO), digital display	1%
Methemoglobin Saturation (% SpMet), digital display	0.1%
Carboxyhemoglobin Saturation (% SpCO), continuous bar display	5%
Carboxyhemoglobin Saturation (% SpMet), continuous bar display	.5, 1-5, 7.5, 10, 15, >20%
Pulse Rate (bpm)	1

Interfering Substances

Carboxyhemoglobin may erroneously increase oxygen saturation 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

Internally powered by 4 "AA" Alkaline batteries

Isolation

No external power or ground connection, internally powered only

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 1060 mbar pressure
	-1,000 ft to 18,000 ft (-304 m to 5,486 m)

Circuitry

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

Display

Type	LED, 7-segment
Data Displayed	Pulse Rate, SpO2 %, % SpCO, % SpCO bar, %SpMet, %SpMet bar, alarm status, alarm silenced status, low Signal IQ, battery statusand SpCO/SpMet connected

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)
Sensor condition alarms
System failure and battery low alarms

Physical characteristics

Dimensions:	6.2" x 3.0" x 1.4" (15.8 cm x 7.6cm x 3.6 cm)
Weight:	13oz. (0.32 kg)

510(k) SUMMARY

Modes

Averaging mode:	2, 4, 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% SpO2 against a laboratory CO-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which 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% SpO2 against a laboratory CO-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

3 The Masimo SET Technology with LNOP Neo sensors has been validated for neonatal 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% SpO2 against a laboratory CO-oximeter and ECG monitor. 1% has been added to the saturation accuracy to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation which encompasses 68% of the population..

4 The Masimo SET Rainbow Technology with Rainbow DC-dc sensors have been validated in human blood on healthy adult volunteers against a laboratory CO-oximeter from 1-40% for carboxyhemoglobin and 1-15% for methemoglobin. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

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 which encompasses 68% of the population.

6. This represents approximate run time at lowest indicator brightness, using a 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.

Biocompatibility Testing

All patient contact materials were tested as Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days) as defined ISO-10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests. All patient contacting material **passed**.

Nonclinical tests performed that support a determination of substantial equivalence.

The Masimo Rainbow SET® Rad-57 cm and m Pulse CO-Oximeter and accessories 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 Rainbow SET® Rad-57 cm and m Pulse CO-Oximeter and accessories 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.

510(k) SUMMARY

Clinical studies were performed using the Masimo Rainbow SET® Rad-57 cm and m Pulse CO-Oximeter 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.

The Masimo SET Rainbow Technology with Rainbow DC-dc sensors have been validated in human blood on healthy adult volunteers against a laboratory CO-oximeter from 1-40% for carboxyhemoglobin and 1-15% for methemoglobin. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

Conclusions

The results of the **environmental testing** demonstrated that the Masimo Rainbow SET® Rad-57 cm and m Pulse CO-Oximeters and accessories **met** the requirements of Reviewers Guidance for Premarket Submissions - November 1993.

The results of the **biocompatibility testing** demonstrates the all patient contacting material **met** the requirements of ISO-10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests for Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days).

The results of the **bench testing** demonstrates that the Masimo Rainbow SET® Rad-57 cm and m Pulse CO-Oximeters **meet** their performance requirements.

The results of the **clinical testing** demonstrates that the Masimo Rainbow SET® Rad-57 cm and m Pulse CO-Oximeters and accessories **meet** their performance requirements during no motion and motion conditions and low perfusion conditions.

The **non-clinical and clinical testing** performed demonstrates that the Masimo Rainbow SET® Rad-57 cm and m Pulse CO-Oximeters and accessories are safe, effective, and performs as well as the predicate device, the Masimo SET® Rad-57 Pulse CO-Oximeter, and therefore, it is substantially equivalent to the Masimo SET® Rad-57 Pulse CO-Oximeter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

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

Re: K053477
Trade/Device Name: Masimo SET Rad 57 cm and
m Pulse CO-Oximeters
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 13, 2005
Received: December 14, 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.

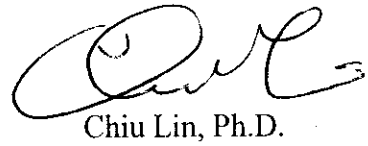
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.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

Enclosure

Section 4 - Indications for Use

510(k) Number (if known):

Device Name: Masimo SET Rad 57 cm and m Pulse CO-Oximeters

Indications For Use:

The Masimo SET® Rad-57 cm Pulse CO-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) and carboxyhemoglobin and methemoglobin saturation or methemoglobin (measured by an SpCO/SpMet sensor). The Masimo SET® Rad-57 cm Pulse CO-Oximeter and accessories are indicated for use with 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 Masimo SET® Rad-57 m Pulse CO-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) and methemoglobin saturation or methemoglobin (measured by an SpCO/SpMet sensor). The Masimo SET® Rad-57 m Pulse CO-Oximeter and accessories are indicated for use with 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.

Prescription Use ___X_____ AND/OR **Over-The-Counter Use** _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] General Hospital
[illegible] Dental Devices
K053477