Section 5: 510(k) Summary

K091241

Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7001
Contact:	Marguerite Thomlinson, Manager of Regulatory Affairs
Date Summary Prepared:	August 14, 2009
Trade Name	Masimo Rainbow SET® Rad 87 CO-Oximeter and Accessories
Common Name	Pulse Oximeter and Sensor
Regulation Number:	21 CFR 870.2700
Regulation Name:	Oximeter
Regulation Class:	Class II
Product Code	DQA, BZQ, DPZ, JKS
Substantially Equivalent Devices	Masimo Rainbow SET® Rad 87 Pulse CO-Oximeters and Accessories, 510(k) Number – K080238 Oridion Capnography Inc., Capnostream 20 with Integrated Pulmonary Index, 510(k) Number – K082268 Andromed Inc., Biological Sound Monitor (BSM) Sensor 510(k) Number – K021389

NOV - 6 2009

Description of the Device

The Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories (Rad 87) include the MX board with Masimo Rainbow SET technology.

The Rad 87 provides noninvasive monitoring of arterial oxygen saturation (%SpO_2), pulse rate, carboxyhemoglobin saturation (%SpCO), methemoglobin saturation (%SpMet), total hemoglobin concentration (g/dl SpHb), and/or respiratory rate (RR). Other information displayed by the Rad 87 includes: Low Signal IQ (Low SIQ), Perfusion Index (PI), Pleth Variability Index (PVI), Total Arterial Oxygen Content (SpOC), Respiratory Signal Quality (RSQ), alarm status, alarm silence, battery life, sensor status, and trends. The Rad 87 has output interfaces include: Nurse Call analog output, and RS-232 serial output.

The Rad 87 in this filing are the same as the Rad-87 in the K080238 filing, but with the addition of respiratory rate monitoring.

Intended Use/Indications for Use

The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RR). The Masimo Rainbow SET® Rad 87 Pulse CO-

Section 5: 510(k) Summary

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.

Principles of Operation

SpO_2 and Pulse Rate
Pulse oximetry is governed by the principles that 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. The amount of arterial blood in tissue changes with the pulse (photoplethysography). Therefore the amount of light, absorbed by the varying quantities of arterial blood, changes accordingly.

SpCO, SpMet, and SpHb General Description
The Rad-87 include the Masimo Rainbow SET technology for SpCO, SpMet and SpHb measurements, based on the same principles of pulse oximetry. The Masimo Rainbow SET technology uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, blood with oxidized hemoglobin and blood plasma.

Once the Masimo Rainbow SET technology receives the signal from the sensor, it calculates the patient's functional oxygen saturation (SpO2), fractional concentration of carboxyhemoglobin (SpCO), fractional concentration of methemoglobin (SpMet), total hemoglobin concentration (SpHb) and pulse rate.

Respiratory Rate General Description
The Masimo Rainbow SET technology also provides respiratory rate measurements, based on vibratory signals from respiratory sounds.

Method of Operation

SpO_2, SpCO, SpMet, and SpHb
The instrument (Rad 87) is turned on. A sensor is attached to a patient's finger. The other end of the sensor is attached to a patient cable. The other end of the patient cable is connected to the Dual Channel cable or directly to the instrument. The connection of the patient cable to the Dual Channel cable is only needed when pulse CO-oximetry monitoring is concurrent with respiratory rate monitoring.

The instrument will begin continuously displaying the patient's pulse rate and SpO_2 value. Depending on the type and/or configuration of the instrument, monitoring information would also include SpCO, SpMet, SpHb, PVI, and/or SpOC. The practitioner can then use the information 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 sensor is removed (and disposed of if it is a single use device), and the power to the instrument is turned off.

Respiratory Rate
The instrument (Rad 87) is turned on. A sensor is attached to a patient's neck. The other end of the sensor is connected to a patient cable. The other end of the cable is connected to the Dual Channel cable. The Dual Channel cable is then connected to the instrument.

The instrument will begin continuously display the patient's respiratory rate. The practitioner can then use the information 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 patient cable is disconnected from the sensor, the sensor is disposed and the power to the instrument is turned off.

Section 5: 510(k) Summary

Specifications

The specifications for the Rad 87 are the following:

FEATURES	SPECIFICATIONS
Display Ranges	
	Oxygen Saturation (SpO_2): 0-100% Pulse Rate (beat per minute or bpm): 25-240 bpm Carboxyhemoglobin Saturation (SpCO): 0-99% Methemoglobin Saturation (SpMet): 0-99.9% Total Hemoglobin (SpHb): 0-25 g/dL Respiratory Rate (RR): 0-150 breaths per minute Total Oxygen Concentration (SpOC): 0-35 ml/dl Perfusion Index: 0.02-20% Pleth Variability Index: 0-100%
Accuracy	See Footnotes 1, 2, 3, 4, 5, 6, and 7
SpO_2, No Motion	60-80 ± 3%, adults/pediatrics/infants 70-100 ± 2%, adults/pediatrics/infants; ± 3%, neonates
SpO_2, Motion	70-100 ± 3%, adults/pediatrics/infants/neonates
SpO_2, Low Perfusion	70-100 ± 2%, adults/pediatrics/infants/neonates
Pulse Rate, No Motion	25-240 ± 3 bpm, adults/pediatrics/infants/neonates
Pulse Rate, Motion	25-240 ± 5 bpm, adults/pediatrics/infants/neonates
Pulse Rate, Low Perfusion	25-240 ± 3 bpm, adults/pediatrics/infants/neonates
SpCO	1-40 ± 3%, adults/pediatrics/infants
SpMet	1-15 ± 1%, adults/pediatrics/infants/neonates
SpHb	8-17 ±1 g/dl (arterial or venous), adults/pediatrics/infants
RR	4-70 ± 1 breath per minute, adults (> 30kg)
General	
Resolution	SpO_2: 1% Pulse Rate: 1 bpm SpCO: 1% SpMet: 0.1% SpHb: 0.1 g/dl RR: 1 breath per minute
Measurements	Low Signal IQ Perfusion Index (PI) Total Oxygen Concentration (SpOC) Pleth Variability Index (PVI) Respiratory Signal Quality (RSQ)
Electrical	
Power (AC)	Voltage Input Range: 100-240 VAC, 47-63 Hz
Batteries	Rechargeable
Circuitry	Microprocessor controlled Automatic self-test of pulse CO-oximeter when powered on Automatic setting of default parameters Automatic alarm messages Trend data output
Firmware	Rainbow SET technology, MX Board/Circuitry
Mechanical	
Material	Polycarbonate/ABS Blend

Section 5: 510(k) Summary

FEATURES	SPECIFICATIONS
Environmental	
Operating Temperature	32 to 122°F (0 to 50°C)
Storage Temperature	-40 to 158°F (-40 to 70°C)
Relative Storage Humidity	10 to 95% non-condensing
Operating Altitude	Pressure: 500-1,060 mbar Altitude: -1,000-18,000 ft (-304-5,486m)
Mode & Sensitivity	
SpO_2 Averaging Mode	2, 4, 6, 8, 10, 12 and 16 seconds; FastSat
SpO_2 Sensitivity	APOD, Normal, Maximum
Alarms	
Volume Level Adjustment: Pulse/Tone	OFF; 25% to 100% in 4 increments
Alarm Silence	120 seconds delay; All mute: continuous silence
Out of Limit Alarms: SpO_2, Pulse Rate, SpCO, SpMet, SpHb, RR, PI, PVI	High/low alarms
Sensor Condition Alarm	No Sensor; Sensor Off; Sensor Defect
System	System failure
Battery Alarm	Low battery
Display and Indicators	
Data Display	SpO_2 (%) Pulse rate (bpm) SpCO (%) SpMet (%) SpHb (g/dl) SpHbv(g/dl) RR SpOC(ml/dl) Perfusion Index-PI (%) Pleth Variability Index-PVI (%) Signal IQ Respiratory Signal Quality (RSQ) Sensitivity indicator Sensor status Sensor time Status messages Alarm status Battery status
Output Interface	
Analog output	Nurse Call
Serial Port (RS-232 connector)	PC/printer connection Philips Vuelink RadNet Patient Safety Net Trends
Compliance	
EMC Compliance	EN 60601-1-2, Class B
Electrical Safety	IEC 60601-1, 2nd Edition; UL 60601-1
Radio	802.11 a/b/g
Type of Protection (AC Power)	Class 1
Type of Protection (battery power)	Internally Powered
Degree of Protection-Patient Cable	Type BF-Applied Part
Liquid Ingress-Degree of Protection	IPX1
Mode of Operation	Continuous

Section 5: 510(k) Summary

Footnotes

1 SpO_2, SpCO and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60-100% SpO_2, 0-40% SpCO, and 0-15% SpMet against a laboratory CO-Oximeter. SpO_2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7-135 days old and weighing between 0.5-4.25 kg. Seventy-nine (79) data samples were collected over a range of 70-100% SaO_2 and 0.5-2.5% MetHb with a resultant accuracy of 2.9% SpO_2 and 0.9% SpMet.

2 The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation 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 sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation 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 which encompasses 68% of the population.

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 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.

5 The Masimo sensors have been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

6 SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8-17 g/dl SpHb against a laboratory CO-oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

7 The following substances may interfere with pulse CO-oximetry measurements:

- Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SpO_2 and SpCO measurements
- Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 measurements.
- Very low arterial Oxygen Saturation (SpO_2) levels may cause inaccurate SpCO and SpMet measurements
- Severe anemia may cause erroneous SpO_2 readings.
- Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Elevated levels of total bilirubin may lead to inaccurate SpO_2, SpMet, SpCO and SpHb readings

Section 5: 510(k) Summary

Test Summary

The Rad 87 comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the Rad 87:

- 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 Rad 87 are substantially equivalent to the predicate devices, 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 W-O66-0609
Silver Spring, MD 20993-0002

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

NOV - 6 2009

Re: K091241
Trade/Device Name: Masimo Rainbow SET Rad 87 Pulse CO-Oximeter and Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, BZQ,DPZ, JKS
Dated: October 29, 2009
Received: October 30, 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,

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

Section 4 - Indications for Use

510(k) Number (if known):

Device Name: Masimo Rainbow SET Rad 87 Pulse CO-Oximeter and Accessories

Indications For Use:

The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RR). The Masimo Rainbow SET® Rad 87 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 (Per 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (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)

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

510(k) Number: K091241

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

510(k) Number: _____