Section 5: 510(k) Summary

JUL - 9 2010

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:	May 20, 2010
Trade Name	Masimo Rainbow SET® Radical 7R 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 – K091241 Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and Accessories, 510(k) Number – K080238

Description of the Device

The Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories (Radical 7R) include the MX board with Masimo Rainbow SET technology. The Radical 7R provides noninvasive monitoring of arterial oxygen saturation (%SpO_2), pulse rate (PR), carboxyhemoglobin saturation (%SpCO), methemoglobin saturation (%SpMet), total hemoglobin concentration (g/dl SpHb), and/or respiration rate (RRa). Other information displayed by the Radical 7R includes: Low Signal IQ (Low SIQ), Perfusion Index (PI), Pleth Variability Index (PVI), Total Arterial Oxygen Content (SpOC), Hematocrit (SpHct), Signal Identification Quality (SIQa), Respiration Indicator (RI), alarm status, alarm silence, battery life, sensor status, trends, and pleth waveform. The Radical 7R has output interfaces include: SatShare connection to multi-parameter monitors, Nurse Call analog output, and RS-232 serial output.

Intended Use/Indications for Use

The Masimo Rainbow SET® Radical 7R 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 (RRa). The Masimo Rainbow SET® Radical 7R 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. In addition, the Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are indicated to provide the continuous noninvasive monitoring data obtained from the Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate to multi-parameter devices for the display of those devices.

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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 red and infrared light. The amount of arterial blood in tissue changes with the pulse (photoplethysography). Thus, the amount of light, absorbed by the varying quantities of arterial blood, changes accordingly.

SpCO, SpMet, and SpHb General Description: The Radical 7R includes the Masimo Rainbow SET technology board, which 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 technology board receives the signal from the sensor, it calculates the patient's functional oxygen saturation (SpO_2), fractional concentration of carboxyhemoglobin (SpCO), fractional concentration of methemoglobin (SpMet), total hemoglobin concentration (SpHb) and pulse rate.

Respiratory or Respiration Rate (RRa) General Description: The Masimo Rainbow SET technology also provides respiratory or respiration rate measurements, based on vibratory signals from respiratory sounds.

Comparison to Predicate Device

The Radical 7R in this filing is the same as the Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and Accessories (Radical 7) in the K080238 filing, with the same performance. In addition to all the same product specifications and features of the predicate, the Radical 7R also include respiratory or respiration rate monitoring and touch screen. Below are the specifications for the Radical 7R.

FEATURES	SPECIFICATIONS
Display Range	SpO_2: 0-100%; PR: 25-240 bpm; SpCO: 0-99%; SpMet: 0-99.9%; SpHb: 0-25 g/dL; RRa: 0-70 breaths per minute; SpOC: 0-35 ml/dl SpHct: 0-75%; PI: 0.02-20%; PVI: 0-100%
Accuracy: SpO_2	No Motion (adults/pediatrics/infants): 60-80 ± 3%; 70-100 ± 2%, ± 3%(neonates) Motion (adults/pediatrics/infants/neonates): 70-100 ± 3% Low Perfusion (adults/pediatrics/infants/neonates): 70-100 ± 2%
Accuracy: PR	No Motion (adults/pediatrics/infants/neonates): 25-240 ± 3 bpm Motion (adults/pediatrics/infants/neonates): 25-240 ± 5 bpm Low Perfusion (adults/pediatrics/infants/neonates): 25-240 ± 3 bpm
Accuracy: SpCO	1-40 ± 3%, adults/pediatrics/infants
Accuracy: SpMet	1-15 ± 1%, adults/pediatrics/infants/neonates
Accuracy: SpHb	8-17 ±1 g/dl (arterial or venous), adults/pediatrics
Accuracy: RRa	4-70 ± 1 breath per minute, adults
Resolution	SpO_2: 1%; PR: 1 bpm; SpCO: 1%; SpMet: 0.1%; SpHb: 0.1 g/dl; RRa: 1 breath per minute
Measurements	Low Signal IQ, PI, SpOC, SpHct, PVI, SIQa, RI
Power	AC Input Range: 100-240 VAC, 47-63 Hz; Rechargeable batteries
Environmental	Operating temperature: 32-122°F (0 to 50°C); Storage temperature: -40 to 158°F (-40 to 70°C); Relative Humidity: 10-95% non-condensing
SpO_2 Averaging Mode/ Sensitivity	Averaging: 2, 4, 6, 8, 10, 12 and 16 seconds; FastSat Sensitivity: APOD, Normal, Maximum
Alarm	Volume (pulse/tone): OFF; 25% to 100% in 4 increments; Silence: 120 sec delay; All mute-continuous silence Out of limit (high/low): SpO_2, Pulse Rate, SpCO, SpMet, SpHb, RRa, PI, PVI Sensor condition: No Sensor, Sensor Off, Sensor Defect Other: system failure, low battery
Display/ Indicators	SpO_2 (%), PR (bpm), SpCO (%), SpMet (%), SpHb (g/dl), SpHbv(g/dl), RRa, SpOC(ml/dl), SpHct (%), PI (%), PVI (%), Pleth waveform, Signal IQ, SIQa, RI Sensitivity indicator, Sensor status/ time/ messages, Alarm status, Battery status

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FEATURES	SPECIFICATIONS
Output Interface	Satshare: connection to Multiparameter monitors (SpO_2 only) Serial Port (RS-232): PC/printer, Vuelink, Spacelabs Flexport, RadNet, PSN, Trends
Compliance	EMC: EN 60601-1-2, Class B Electrical Safety: IEC 60601-1 and UL 60601-1, Class 1 (AC Power), Internally Powered, Patient Cable-Type BF applied part, Satshare cable-Type CF applied part
Operation Mode	Continuous

Clinical Summary

Clinical Studies: 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. SpHb accuracy has been validated on healthy adult 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. The variation in these studies equals plus or minus one standard deviation encompasses 68% of the population.

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.

Clinical Results: No device-related adverse events. The clinical studies were performed in accordance with ISO 9919:2005. The studies resulted in accuracies (rms) of equal to or less than the respective accuracies as stated above in the Radical 7R specifications.

Non-Clinical Summary

The Radical 7R complies with the voluntary standards as detailed in this submission. Laboratory testing for biocompatibility, safety and environmental was conducted to verify that the Radical 7R met all design specifications and was substantially equivalent to the predicate device.

Conclusions

The information in this 510(k) submission demonstrates that the Radical 7R is 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-G609
Silver Spring, MD 20993-0002

JUL - 9 2010

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

Re: K100428
Trade/Device Name: Masimo Rainbow SET Radical 7R Pulse CO- Oximeter and accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulation Class: II
Product Code: DQA
Dated: June 28, 2010
Received: June 30, 2010

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. 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); 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anrsthesiology, Geberal 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 Radical 7R Pulse CO-Oximeter and Accessories

Indications For Use:

The Masimo Rainbow SET® Radical 7R 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 (RRa). The Masimo Rainbow SET® Radical 7R 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. In addition, the Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories are indicated to provide the continuous noninvasive monitoring data obtained from the Masimo Rainbow SET® Radical 7R Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate to multi-parameter devices for the display of those devices.

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: K100428