K082052

OCT 1 0 2008

510(k) SUMMARY

Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 949-297-7000 FAX 949-297-7001
Company Contact:	Marguerite Thomlinson, Manager of Regulatory Affairs
Date Summary Prepared:	July 16, 2008
Trade Name	Masimo Rainbow SET RadCheck Pulse CO-Oximeter and Accessories
Common Name	Oximeter Sensor
Classification Name and Product Code:	Oximeter (74DQA) (870.2700) Cable, Transducer and Electrode (74DSA) (870.2900)
Substantially Equivalent Devices:	Masimo Rainbow SET Rad 57t Pulse CO-Oximeters and Accessories, 510(k) Number K080238

Device Description

The Masimo Rainbow SET® RadCheck Pulse CO-Oximeter and Accessories (RadCheck) have modified intended use/indications for use in comparison to the Rad 57t Pulse CO-Oximeters and Accessories (Rad 57t) in the K080238 filing. The main difference is that the RadCheck in this filing is for spot checking, whereas the Rad 57t in K0808238 is for continuous monitoring. The keypad membrane and the software of the RadCheck also differ from the Rad 57t.

The RadCheck in this filing is similar in construction to the Rad 57t in the K0808238 filing, including the 12-wavelength technology for the measurement of total hemoglobin. The performance of the Radcheck is similar to the Rad 57t. Similar to the Rad 57t, the RadCheck provides noninvasive monitoring of arterial oxygen saturation (%SpO_2), pulse rate, and total hemoglobin concentration (g/dl SpHb). Other information displayed by the RadCheck include: Low Signal IQ (Low SIQ), Perfusion Index (PI), Total Arterial Oxygen Content (SpOC), battery life, and sensor status.

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Predicate Device

The predicate device used in this filing is the Masimo Rainbow SET® Rad 57t Pulse CO-Oximeter (Rad 57t) and Accessories, 510(k) Number K080238.

Intended Use

The Masimo Rainbow SET® RadCheck Pulse CO-Oximeter and Accessories are indicated for noninvasive spot checking of functional saturation of arterial hemoglobin (SpO2), pulse rate, and total hemoglobin (SpHb). The Masimo Rainbow SET® RadCheck Pulse CO-Oximeter and Accessories are indicated for use, by trained personnel, with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in clinical and non-clinical settings.

Technology Comparison

The Masimo Rainbow SET® RadCheck Pulse CO-Oximeter (Rad 57 Spotcheck) is substantially equivalent in design, principles of operation, materials, and performance to predicate device (the Rad 57t).

Similar to the Rad 57t, the RadCheck is designed, configured, and manufactured for full compatibility with Masimo Rainbow pulse CO-Oximeter sensors with SpHb capabilities (K080238).

The RadCheck performance is equivalent to those of the Rad 57t, as following:

FEATURES	SPECIFICATIONS
Display Ranges	
	Saturation (SpO_2): 0% - 100% Pulse Rate (bpm): 25 – 240 bpm Total Hemoglobin (SpHb): 0-25 g/dl Total Oxygen Concentration (SpOC): 0-35 ml/dl Perfusion Index: 0.02% - 20%
Accuracy: SpO_2 and Pulse Rate	**See Footnotes 1, 2, 3, 4, and 5**
Accuracy – SpO_2 During No Motion Conditions	Adults, Pediatrics: 60% - 80% ± 3% Adults, Pediatrics: 70% - 100% ±2% Adults, Pediatrics: 0% - 69% unspecified
Accuracy – SpO_2 During Motion Conditions	Adults, Pediatrics: 70% - 100% ± 3% Adults, Pediatrics: 0% - 69% unspecified
Accuracy – SpO_2 Low Perfusion	Adults, Pediatrics: 70% - 100% ± 2% Adults, Pediatrics: 0% - 69% unspecified
Accuracy – Pulse Rate During No Motion Conditions	Adults, Pediatrics: 25 - 240 ± 3 bpm
Accuracy – Pulse Rate During Motion Conditions	Adults, Pediatrics: 25 - 240 ± 5 bpm
Accuracy – Pulse Rate Low Perfusion	Adults, Pediatrics: 25 - 240 ± 3 bpm

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FEATURES	SPECIFICATIONS
Accuracy: SpHb	
Accuracy – SpHb During No Motion Conditions	Adults, Pediatrics: 8 - 17 g/dl ±1 g/dl • 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.
General	
Resolution	SpO_2: 1% Pulse Rate: 1 bpm SpHb: 0.1 g/dl
Measurements	Low Signal IQ Perfusion Index (PI) Total Oxygen Concentration (SpOC)
Interfering Substances	• Elevated levels of Methemoglobin (MetHb) may lead to inaccurate SpO_2 measurements • Elevated levels of Carboxyhemoglobin (COHb) may lead to inaccurate SpO_2 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, and SpHb readings
Electrical	See Footnote 6
Batteries	Non-Rechargeable
Circuitry	Microprocessor controlled
Firmware	Rainbow SET technology, MX-1 Board/Circuitry
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 – SpO_2	Maximum sensitivity mode fixes perfusion limit to 0.02%
Alarms	
System	System failure
Battery Alarm	Low battery

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FEATURES	SPECIFICATIONS
Display and Indicators	
Data Display	SpO_2 (%) Pulse rate (bpm) SpHb (g/dl) Perfusion index (%) SpOC (ml/dl) Signal IQ Pulse indicator Sensor life indicator Sensor status Status messages Battery status
Compliance	
EMC Compliance	EN 60601-1-2, Class B
Electrical Safety	IEC 60601-1, UL 60601-1
Type of Protection (battery power)	Internally Powered
Degree of Protection-Patient Cable	Type BF-Applied Part
Enclosed Degree of Ingress Protection from Solids/ Liquids	IPX1
Mode of Operation	Spot check

Footnotes

1 SpO_2 accuracy was determined by testing on healthy adult volunteers in the range of 60-100% SpO_2 against a laboratory CO-Oximeter.

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 weight.

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 If the batteries are to be stored for extended periods of time, it is recommended that they be stored between -20 to +30°C, and at a relative humidity less than 85%. If stored for a prolonged period at environmental conditions beyond these limits, overall battery capacity may be diminished, and lifetime of the batteries may be shortened.

Test Summary

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

- 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 Rainbow SET® RadCheck Pulse CO-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
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2008

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

Re: K082052
Trade/Device Name: Masimo Rainbow SET RadCheck Pulse CO-Oximeter and Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 16, 2008
Received: July 21, 2008

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

Indications for Use

510(k) Number (if known): _____

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

Indications For Use:

The Masimo Rainbow SET RadCheck Pulse CO-Oximeter and Accessories are indicated for noninvasive spot checking of functional saturation of arterial hemoglobin (SpO2), pulse rate, and total hemoglobin (SpHb). The Masimo Rainbow SET RadCheck Pulse CO-Oximeter and Accessories are indicated for use, by trained personnel, with adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused in clinical and non-clinical settings.

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

510(k) Number: K082052

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)