510(k) SUMMARY

K091057

JUL - 9 2009

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:	April 10, 2009
Trade Name	Masimo Rainbow SET Pronto Pulse CO-Oximeter and Accessories
Common Name	Oximeter
Classification Name and Product Code:	Oximeter (74DQA) (870.2700) Cable, Transducer and Electrode (74DSA) (870.2900)
Substantially Equivalent Devices:	Masimo Rainbow SET RadCheck Pulse CO-Oximeters and Accessories, 510(k) Number K082052

Device Description

The Masimo Rainbow SET® Pronto Pulse CO-Oximeter and Accessories in this filing are the same as the Rainbow SET® RadCheck Pulse CO-Oximeter and Accessories in K082052. The reason for this filing is to clarify the intended use and the labeling of the device.

Predicate Device

The predicate device used in this filing is the Masimo Rainbow SET® RadCheck Pulse CO-Oximeter and Accessories, 510(k) Number K082052.

Intended Use

The Masimo Rainbow SET® Pronto Pulse CO-Oximeter and Accessories are indicated for noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SpO_2), pulse rate, and total hemoglobin concentration (SpHb). The Masimo Rainbow SET® Pronto Pulse CO-Oximeter and Accessories are indicated for use, by trained personnel, with adult and pediatric individuals during both no motion and motion conditions, and for individuals who are well or poorly perfused in clinical and non-clinical settings (e.g., hospitals, hospital-type facilities, mobile environments, homes, clinics, physician offices, blood donation facilities, and ambulatory surgery centers).

Technology Comparison

The Masimo Rainbow SET® Pronto Pulse CO-Oximeter is the same in design, principles of operation, materials, and performance to the predicate device (the RadCheck).

510(k) SUMMARY

The Pronto has the following specifications:

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	See Footnotes 1, 2, 3, 4, 5, 6, and 7
SpO_2, No Motion Conditions	Adults, Pediatrics: 60-80% ± 3%; 70-100% ±2%
SpO_2, Motion Conditions	Adults, Pediatrics: 70-100% ± 3%
SpO_2, Low Perfusion	Adults, Pediatrics: 70-100% ± 2%
Pulse Rate, No Motion Conditions	Adults, Pediatrics: 25-240 ± 3 bpm
Pulse Rate, Motion Conditions	Adults, Pediatrics: 25-240 ± 5 bpm
Pulse Rate, Low Perfusion	Adults, Pediatrics: 25-240 ± 3 bpm
SpHb, No Motion Conditions	Adults, Pediatrics: 8-17 g/dl ±1 g/dl (Arterial or Venous)
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)
Electrical	See Footnote 8
Batteries	Non-rechargeable alkaline batteries
Circuitry	Microprocessor controlled
Firmware	Rainbow SET technology, MX 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

510(k) SUMMARY

FEATURES	SPECIFICATIONS
Display and Indicators	
	SpO_2 (%) Pulse rate (bpm) SpHb (g/dl) SpHbv (g/dl) Perfusion index (%) SpOC (ml/dl) Signal IQ Pulse indicator Spot Check Progress Sensor Use 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
Enclosure Degree of Protection	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 SpHb accuracy has been validated with (arterial/venous) blood from 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 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

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

- 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® Pronto 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

JUL - 9 2009

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

Re: K091057
Trade/Device Name: Masimo Rainbow SET Pronto Pulse CO-Oximeter and Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 5, 2009
Received: June 16, 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

Susan Runner, D.D.S., M.A.
Acting 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): K091057

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

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)

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

510(k) Number: K091057