K111403

DEC 3 0 2011

510(k) SUMMARY

Applicant:	Masimo Corporation 40 Parker Irvine, CA 92618 949-297-7000 FAX 949-297-7592
Company Contact:	Anil Bhalani Director of Regulatory affairs
Date Summary Prepared:	November 10, 2011
Trade Name:	Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories
Common Name:	Oximeter
Classification Name/ Product Code:	Oximeter (21CFR 870.2700/ Product Code: DQA)
Predicate Device:	K100403- Masimo Rainbow SET Pronto Pulse CO-Oximeter and Accessories (Pronto-7)

Device Description

The Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories include the noninvasive technology spot check of measurement for functional saturation of arterial oxygen hemoglobin (SpO_2), pulse rate and total hemoglobin concentration (SpHb), which is based on the same technology of the predicate device. This submission introduces two new sensor sizes (medium and small) and an optional Maximum Sensitivity Mode that extends the detection range for SpHb.

Intended Use/ Indications for Use

The Masimo Rainbow SET Pronto-7 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-7 Pulse CO-Oximeter and Accessories are indicated for use by trained personnel, with adult and pediatric individuals, in clinical and non-clinical settings (e.g., hospitals, hospital-type facilities, home, clinics, physician offices, and ambulatory surgery centers).

Technology Comparison

The Fundamental Scientific Technology of the previously cleared Pronto-7 device and Sensor and that of the Pronto-7 device and sensors is the same.

Device	Masimo Rainbow SET Pronto Pulse CO-Oximeter and Accessories	
	K100403	K111403 (Subject Device)
Display Range	Saturation (SpO_2): 0-100% Pulse Rate: 30-250 bpm Total Hemoglobin (SpHb): 0-25 g/dL Perfusion Index (PI): 0.02-20%	Same
Accuracy Adults and Pediatrics (> 30kg)	SpO_2: 70-100±2%	Same
	Pulse Rate: 30-250±3 bpm	Same
	Normal Sensitivity Mode: SpHb: 6-18 g/dl ±1 g/dL	Normal Sensitivity Mode: Same Maximum Sensitivity Mode: SpHb: 4.5-20 g/dl ±1.1 g/dL
Resolution	SpO_2: 1%; Pulse Rate: 1 bpm, SpHb: 0.1 g/dL	Same
AC Power	Voltage Input: 100-240 VAC, 50-60 Hz; Max Power Consumption: 15 VA	Same
Batteries	Rechargeable lithium polymer battery	Same
Temperature	Operating: 41 to 104^{0}F (5 to 40^{0}C) Storage: -40^0 to 158^{0}F (-40 to 70^{0}C)	Same
Relative Humidity	5 to 95% non-condensing	Same
Operating Altitude	500 to 1,060 mbar; -1,000 to 18,000 ft (-304 to 5,486m)	Same
Alarm	System Failure; Low Battery Alarm	Same
Display and Indicators	SpO_2 (%); Pulse Rate (bpm); SpHb (g/dl); Perfusion Index (%); Pleth Waveform; Sensor Status; Status Messages; Battery Status	Same
Connection/ Output	Wireless: Bluetooth 2.0; Wi-Fi *b/g,* Flash Memory: Micro SD card slot	Same
Earphone jack	Connection for standard 3.5 mm earphone jack	Same
EMC/Electrical Safety Compliance	EN 60601-1 -2, Class B IEC 60601-1, UL 60601-1, CAN/CSA STD C22.2, Internally Powered, AC Power Class 2, Compliance Type BF-Applied Part, IPX1, Class 2	Same
Mode of Operation	Spot Check	Same

Performance Data Summary

SpO_2 accuracy has been validated in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation. Pronto-7 measurements on volunteers induced hypoxia in the range of 70-100% SpO_2 are compared against a laboratory CO-Oximeter and ECG monitor. SpHb accuracy has been validated with (arterial/ venous) blood from healthy adult male and female volunteers and on patients with light to dark skin pigmentation in the ranges of 6-18 g/dl SpHb (Normal Sensitivity Mode) and 4.5-20 g/dl SpHb (Maximum Sensitivity Mode), with Pronto-7 measurements compared against a laboratory CO-Oximeter. Pulse rate accuracy has been validated on healthy adult male and female volunteers and on patients with light to dark skin pigmentation in the range of 40-110 bpm. The variation in these studies equals plus or minus one standard deviation encompasses 68% of the population.

Results: The studies were performed in accordance with ISO 9919:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. The studies resulted in SpO_2 accuracy (rms) of ± 2%, pulse rate accuracy (rms) of ± 3bpm, and SpHb accuracy (rms) of ± 1g/dl (Normal Sensitivity Mode) and ± 1.1g/dl (Maximum Sensitivity Mode).

Non-Clinical Data Summary

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

Conclusions

The information in this 510(k) submission demonstrates that the Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories are substantially equivalent to the predicate device with respect to safety and effectiveness.

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

Mr. Anil Bhalani
Director of Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

DEC 3 0 2011

Re: K111403
Trade/Device Name: Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, GLY
Dated: December 22, 2011
Received: December 28, 2011

Dear Mr. Bhalani:

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 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 Pronto-7 Pulse CO-Oximeter and Accessories

Statement of Indications for Use:

The Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories are indicated for noninvasive spot checking of functional saturation of arterial oxygen hemoglobin (SP02), pulse rate, and total hemoglobin concentration (SpHb). The Masimo Rainbow SET Pronto-7 Pulse CO-Oximeter and Accessories are indicated for use by trained personnel, with adult and pediatric individuals, in clinical and non-clinical settings (e.g., hospitals, hospital-type facilities, home, clinics, physician offices and ambulatory surgery centers).

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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

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