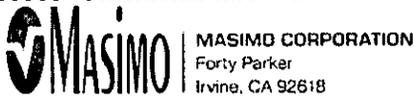


K111888



SEP 23 2011

**510(k) Summary**

**Submitter:** Masimo Corporation  
40 Parker  
Irvine, CA 92618  
(949) 297-7000  
Fax: (949) 297-7592

**Contact Person:** David Collette  
Senior Manager, Regulatory Affairs

**Date Prepared:** August 24, 2011

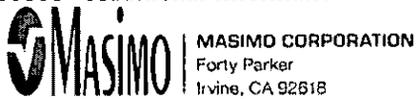
**Trade name:** Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors

**Classification Name:** Oximeter Sensor, (21 CFR 870.2700)

**Predicate Device:** K101896, LNCS/M-LNCS Oximetry Sensors

**Device Description:** The Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors are pulse oximetry sensors. They measure tissue oxygenation non-invasively through infrared emitters and detectors. They are fully compatible for use with Masimo SET and Masimo Rainbow SET instruments.

**Indications for Use:** The Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate (measured by an SpO<sub>2</sub> sensor) for use with adult, pediatric, infant, 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.



**Comparative Analysis:**

The Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors are substantially equivalent to the predicate device in the design, principles of operation, and performance. The subject and predicate device operate on identical principles of non-invasive optical assessment of tissue oxygenation using emitters and detectors.

**Functional/Safety Testing:**

The following non-clinical testing was conducted to verify that the Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors met all design specifications: Ambient light rejection, noise rejection, electrostatic discharge, voltage breakdown, bend testing, off-patient detection, tape strip life cycle, current transfer ratio, light piping, electrocautery noise rejection, sensor skin temperature, moisture resistance and cleaning, drop, storage and operating conditions, bend and pull.

**Conclusion:**

The Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors are substantially equivalent to the predicate device.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -W066-G609  
Silver Spring, MD 20993-0002

Mr. Anil Bhalani  
Director, Regulatory Affairs  
Masimo Corporation  
40 and 50 Parker  
Irvine, California 92618

SEP 23 2011

Re: K111888  
Trade/Device Name: Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: II  
Product Code: DQA  
Dated: August 24, 2011  
Received: August 25, 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.

Page 2 – Mr. Bhalani

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,



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

**Appendix 2 -- Indications for Use Statement**

**510(k) Number (if known):**

**Device Name:** Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors

**Indications for Use:**

The Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate (measured by an SpO<sub>2</sub> sensor) for use with adult, pediatric, infant, 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    
(Part 21 CFR 801 Subpart D)

**AND/OR**

**Over-The-Counter Use** \_\_\_\_\_  
(21 CFR 807 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Page 1 of 1



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

510(k) Number:   K111888  

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