MASIMO CORPORATION
Forty Parker
Irvine, CA 92618

K101896

510(k) SUMMARY

Submitted by:	Masimo Corporation 40 Parker, Irvine, CA 92618 Phone: 949-297-7000, Fax: 949-297-7592
Company Contact:	Anil Bhalani, Director of Regulatory Affairs
Date Summary Prepared:	September 17, 2010
Trade Name	LNCS/ M-LNCS Oximetry Sensors
Common Name	Oximeter Sensor
Regulation Number:	21 CFR 870.2700
Regulation Name/Product Code:	Oximeter/ DQA
Substantially Equivalent Devices:	LNCS Oximetry Sensors, 510(k) No. K051212

OCT 2 1 2010

Device Description:

The LNCS/M-LNCS Oximetry Sensors are fully compatible for use with instruments which include or compatible with the following technologies:

- Masimo SET technology
- Masimo Rainbow SET technology
- Nellcor technology
- Philips FAST-SpO_2 technology

Intended Use/ Indications for Use

The LNCS/M-LNCS Sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 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.

Comparison to Predicate Device

The sensors in this filing are the same indications for use, intended use, performance and principle of operations, as the respective predicate sensors (K051212).

The main difference is that the sensors in this filing have a lower profile in comparison to the predicates, for optimal fit and comfort for patients. The design is optimized or improved by the removal of excess inner wrap materials and an alternate molding compound in LED assemblies. The sensor model names in this filing and the corresponding predicate sensor model names are the same. See Table 1 below for the sensor model names and comparison descriptions.

Additionally, the upper pulse rate accuracy range for Masimo technology has been revised from 240 bpm to 300 bpm. See Table 2 below for the sensor specifications.

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Table 1: Sensor Models for LNCS and M-LNCS Oximetry Sensors

Pending Masimo LNCS and M-LNCS Oximetry Sensors	Predicate Masimo LNCS/M-LNCS Oximetry Sensors in K051212	Comparison Description (pending vs. predicate)
LNCS Inf-L: Infant Adhesive Sensor	LNCS Inf-L	Lower profile design for optimized fit and patient comfort. Same indications for use, intended use, patient populations, patient weight, measurement sites, performance, and biocompatible materials.
LNCS/M-LNCS Inf : Infant Adhesive Sensor	LNCS/M-LNCS Inf	
LNCS/M-LNCS Inf-3: Infant Adhesive Sensor	LNCS/M-LNCS Inf-3	
LNCS Neo-L: Neonatal Adhesive Sensor	LNCS Neo-L	
LNCS/M-LNCS Neo: Neonatal/Adult Adhesive Sensor	LNCS/M-LNCS Neo	
LNCS/M-LNCS Neo-3: Neonatal/Adult Adhesive Sensor	LNCS/M-LNCS Neo-3	
LNCS NeoPt-L: Neonatal Adhesive Sensor	LNCS NeoPt-L	
LNCS/M-LNCS NeoPt: Neonatal Adhesive Sensor	LNCS/M-LNCS NeoPt	
LNCS/M-LNCS NeoPt-3: Neonatal Adhesive Sensor	LNCS/M-LNCS NeoPt-3	
LNCS/M-LNCS NeoPt-500: Neonatal Adhesive Sensor	LNCS/M-LNCS NeoPt-500	
LNCS/M-LNCS Newborn Neonatal: Neonatal Adhesive Sensor	LNCS/M-LNCS Newborn Neonatal	
LNCS/M-LNCS Newborn Infant/Pediatrics: Infant/Pediatric Adhesive Sensor	LNCS/M-LNCS Newborn Infant/Pediatrics	
Accessories used with Masimo LNCS/M-LNCS Sensors		
LNCS/M-LNCS Inf Series: Replacement Tapes for LNCS/M-LNCS Inf Series Sensors	LNCS/M-LNCS Inf Series Replacement Tapes	Same as predicate.
LNCS/M-LNCS Neo Series: Replacement Tapes for LNCS/M-LNCS Neo Series Sensors	LNCS/M-LNCS Neo Series Replacement Tapes	
LNCS/M-LNCS NeoPt and Newborn Series: Replacement Wraps for LNCS/M-LNCS NeoPt and Newborn Neonatal Series Sensors	LNCS/M-LNCS NeoPt and Newborn Neonatal Series Replacement Wraps	
Red LNC Series: Patient Cables	Red LNC Series Patient Cables	
LNC/M-LNC Series: Patient Cables	LNC/M-LNC Series Patient Cables	
LNCS/M-LNCS and LNC/M-LNC Series: Adapter Cables	LNCS/M-LNCS and LNC/M-LNC Series Adapter Cables	

Table 2: Sensor Specifications for LNCS/M-LNCS Oximetry Sensors

	Accuracy Range	Accuracy: Adult/ Pediatric/ Infant	Accuracy: Neonatal	Predicate Device: Accuracy Range/ Specification
Masimo Technology				
SpO_2, no motion	70-100%	± 2%	± 3%	Same
SpO_2, motion	70-100%	± 3%	± 3%	Same
SpO_2, low perfusion	70-100%	± 2%	± 3%	Same
Pulse rate, no motion	25-300 bpm	± 3 bpm	± 3 bpm	25-240 bpm/ ± 3 bpm

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	Accuracy Range	Accuracy: Adult/ Pediatric/ Infant	Accuracy: Neonatal	Predicate Device: Accuracy Range/ Specification
Masimo Technology				
Pulse rate, motion	25-300 bpm	± 5 bpm	± 5 bpm	25-240 bpm/ ± 5 bpm
Pulse rate, low perfusion	25-300 bpm	± 3 bpm	± 3 bpm	25-240 bpm/ ± 3 bpm
Nellcor/Phillips Fast Technology				
SpO_2, no motion	70-100%	± 2%	± 3%	Same
Pulse rate, no motion	25-240 bpm	± 3 bpm	± 3 bpm	Same

Test Summary

The following non-clinical testing was conducted to verify that the LNCS/M-LNCS Oximetry Sensors met all design specifications: biocompatibility testing, performance testing including bench accuracy testing and visual and validated functional testing.

Conclusion

The results demonstrated that the LNCS/M-LNCS Oximetry Sensors are as safe and effective as the legally marketed predicate devices.

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

OCT 2 1 2010

Re: K101896
Trade/Device Name: Masimo LNCS/M-LNCS Oximetry Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 17, 2010
Received: September 22, 2010

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.

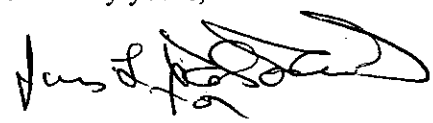
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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): _____

OCT 2 1 2010

Device Name: Masimo LNCS/M-LNCS Oximetry Sensors

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)

K101896

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

510(k) Number: L Schultz