K110723

510(k) SUMMARY

JUL 28 2011

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:	May 11, 2011
Trade Name	M-LNCS and Reprocessed M-LNCS Oximetry Sensors
Regulation Number:	21 CFR 870.2700
Regulation Class:	Class II
Regulation Name:	Oximeter
Common Name:	Oximeter Sensor
Product Code:	NLF, DQA, DSA
Substantially Equivalent Devices:	Masimo LNCS/M-LNCS Oximetry Sensors, 510(k) No. K101896 LNCS Oximetry Sensors-Sterile, 510(k) No. K083622 Reprocessed LNCS Oximetry Sensors, 510(k) No. K083719

Device Description

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

- Masimo SET technology
- Masimo Rainbow SET technology
- Nellcor technology

The M-LNCS series has been validated with Masimo SET Oximetry Technology and on Nellcor's N-200 Pulse Oximeter. The saturation accuracy of the Neonate and Preterm sensors were validated on adult volunteers and 1% was added to account for properties of fetal hemoglobin.

Intended Use/ Indications for Use

The M-LNCS Sensors are indicated for the continuous non-invasive 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.

The Reprocessed M-LNCS Sensors are indicated for the continuous non-invasive 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 Devices

The predicate devices used in this filing are:

510(k) SUMMARY

- LNCS Oximetry Sensors-Sterile, 510(k) No. K083622
- Reprocessed LNCS Oximetry Sensors, 510(k) No. K083719

The sensors in this filing are substantially equivalent to the predicate sensors in the indication for use/intended use. In addition, they have the same performance and principle of operations, and are subjected to the same processes for sterile (ethylene oxide sterilization) and reprocessing as the respective predicate sensors in the cleared K083622 and K083719 filings. The main difference is that the sensors in this filing have a different interfacing connector in comparison to the predicates.

Predicate Devices

Table 1 – Oximetry Sensors, Sterile

M-LNCS Oximetry Sensors (Single-Use and Sterile)	Predicate LNCS Oximetry Sensors (Single-Use and Sterile) in K083622
M-LNCS Adtx-3: Adult Adhesive Sensor	LNCS Adtx-3
M-LNCS Pdtx-3: Pediatric Adhesive Sensor	LNCS Pdtx-3
M-LNCS Inf-3: Infant Adhesive Sensor	LNCS Inf-3
M-LNCS Neo-3: Neonatal Adhesive Sensor	LNCS Neo-3
M-LNCS NeoPt-3: Neonatal Adhesive Sensor	LNCS NeoPt-3
M-LNCS NeoPt-500: Neonatal Adhesive Sensor	LNCS NeoPt-500

Table 2 – Oximetry Sensors, Reprocessed

Reprocessed M-LNCS (Single-Use) Sensors	Predicate Reprocessed LNCS (Single-Use) Sensors in K083719
Reprocessed M-LNCS Adtx: Adult Adhesive Sensor	Reprocessed LNCS Adtx
Reprocessed M-LNCS Adtx-3: Adult Adhesive Sensor	Reprocessed LNCS Adtx-3
Reprocessed M-LNCS Pdtx: Pediatric Adhesive Sensor	Reprocessed LNCS Pdtx
Reprocessed M-LNCS Pdtx-3: Pediatric Adhesive Sensor	Reprocessed LNCS Pdtx-3
Reprocessed M-LNCS Inf: Infant Adhesive Sensor	Reprocessed LNCS Inf
Reprocessed M-LNCS Inf-3: Infant Adhesive Sensor	Reprocessed LNCS Inf-3
Reprocessed M-LNCS Neo: Neonatal Adhesive Sensor	Reprocessed LNCS Neo
Reprocessed M-LNCS Neo-3: Neonatal Adhesive Sensor	Reprocessed LNCS Neo-3
Reprocessed M-LNCS NeoPt: Neonatal Adhesive Sensor	Reprocessed LNCS NeoPt
Reprocessed M-LNCS NeoPt-3: Neonatal Adhesive Sensor	Reprocessed LNCS NeoPt-3
Reprocessed M-LNCS NeoPt-500: Neonatal Adhesive Sensor	Reprocessed LNCS NeoPt-500

Table 3 - Sensor Specifications for Sterile and Reprocessed M-LNCS Sensors

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

510(k) SUMMARY

Test Summary

The following non-clinical testing was conducted and verifies that the sterile and reprocessed M-LNCS Oximetry Sensors met all design specifications: biocompatibility testing, in-house and laboratory validation testing on the sensors after they have been subjected to ethylene oxide sterilization (EO) or the sensors have been reprocessed and subjected to EO sterilization, performance testing including bench accuracy testing and visual and validated functional testing.

Conclusion

The results of the performance data demonstrate that the sterile M-LNCS and Reprocessed 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

Ms. Shelly Harris
Manager of Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

JUL 28 2011

Re: K110723
Trade/Device Name: Masimo M-LNCS Oximetry Sensors Masimo Reprocessed M-LNCS Oximetry Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF, DQA, DSA
Dated: June 14, 2011
Received: June 28, 2011

Dear Ms. Harris:

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/Reporta Problem /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,

Susan Runner

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): K110723

Device Name: Masimo M-LNCS Oximetry Sensors
Masimo Reprocessed M-LNCS Oximetry Sensors

Indications For Use:

The M-LNCS Sensors are indicated for the continuous non-invasive 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.

The Reprocessed M-LNCS Sensors are indicated for the continuous non-invasive 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.

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: K110723