K094046

510(k) SUMMARY

MAY 14 2010

Submitted by:	Masimo Corporation 40 Parker, Irvine, CA 92618 Phone: 949-297-7000; Fax: 949-297-7592
Company Contact:	Marguerite Thomlinson, Manager of Regulatory Affairs
Date Summary Prepared:	May 6, 2010
Trade Name	Reprocessed LNCS Oximetry Sensors
Common Name	Oximeter Sensor
Regulation Number:	21 CFR 870.2700
Regulation Name/ Product Code:	Oximeter/ NLF, DQA
Substantially Equivalent Devices:	Reprocessed LNCS Oximetry Sensors, 510(k) No. K083719

Device Description

The Reprocessed LNCS Oximetry Sensors are fully compatible disposable sensors for use with Masimo SET and Masimo SET compatible pulse oximeter monitors. The Reprocessed LNCS Oximetry Sensors are also compatible with Nellcor and Nellcor compatible pulse oximeter monitors.

Intended Use/ Indications for Use

The Reprocessed 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 in design, performance, and principle of operations, as the respective predicate sensors (K083719). The main difference is that the predicate devices have replaceable tapes and the pending sensors do not have replaceable tapes.

The predicate sensors and the corresponding Reprocessed LNCS Oximetry Sensors in this filing are:

Predicate Reprocessed LNCS Sensors in K083719	Reprocessed LNCS Oximetry Sensors
Infant single-use sensor: Reprocessed LNCS Inf Reprocessed LNCS Inf-3	Infant single-use sensor: Reprocessed LNCS Inf-L Reprocessed LNCS Inf-L-3
Neonatal single-use sensor: Reprocessed LNCS Neo Reprocessed LNCS Neo-3	Neonatal single-use sensor: Reprocessed LNCS Neo-L Reprocessed LNCS Neo-L-3
Neonatal single-use sensor: Reprocessed LNCS NeoPt Reprocessed LNCS NeoPt-3	Neonatal single-use sensor: Reprocessed LNCS NeoPt-L Reprocessed LNCS NeoPt-L-3

510(k) SUMMARY

The sensors in this filing have the same specifications as the predicate devices, which are as following:

Measurement	Accuracy Range	Accuracy: Reprocessed LNCS infant sensors	Accuracy: Reprocessed LNCS neonatal sensors
SpO_2, no motion (Masimo technology)	70-100%	± 2%	± 3%
SpO_2, motion (Masimo technology)	70-100%	± 3%	± 3%
SpO_2, low perfusion (Masimo technology)	70-100%	± 2%	± 3%
Pulse rate, no motion (Masimo technology)	25-240 bpm	± 3 bpm	± 3 bpm
Pulse rate, motion (Masimo technology)	25-240 bpm	± 5 bpm	± 5 bpm
Pulse rate, low perfusion (Masimo technology)	25-240 bpm	± 3 bpm	± 3 bpm
SpO_2, no motion (Nellcor technology)	70-100%	± 2%	± 3%
Pulse rate, no motion (Nellcor technology)	25-240 bpm	± 3 bpm	± 3 bpm

Test Summary

The following non-clinical testing was conducted to verify that the Reprocessed LNCS Sensors met all design specifications: biocompatibility testing including cytotoxicity, sensitization, and skin irritation testing; performance testing including bench accuracy testing; safety testing including process validation of the sterilization procedures, and visual and validated functional testing of all products; and environmental testing including device packaging validation.

Conclusion

The results demonstrated that the Reprocessed LNCS Oximetry Sensors are equivalent to the 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

MAY 14 2010

Ms. Marguerite Thomlinson
Manager of Regulatory Affairs
Masimo Corporation
40 and 50 Parker
Irvine, California 92618

Re: K094046
Trade/Device Name: Masimo LNCS Oximetry Sensors, Masimo Reprocessed LNCS Oximetry Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 12, 2010
Received: April 14, 2010

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. 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): K094046

Device Name: Masimo Reprocessed LNCS Oximetry Sensors

Indications For Use:

The Reprocessed 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.

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)

L Schultz

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

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