K083514 **510(k) SUMMARY**

JUL 30 2009

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| **Submitted by:** | Masimo Corporation<br>40 Parker<br>Irvine, CA 92618<br>949-297-7000<br>FAX 949-297-7001 |
| **Company Contact:** | Marguerite Thomlinson, Manager of Regulatory Affairs |
| **Date Summary Prepared:** | December 12, 2008 |
| **Trade Name** | LNCS Oximetry Sensors |
| **Common Name** | Oximeter Sensor |
| **Classification Name and Product Code:** | Reprocessed, Oximeter (NLF) (870.2700)<br>Oximeter (74DQA) (870.2700)<br>Cable, Transducer and Electrode (74DSA) (870.2900) |
| **Substantially Equivalent Devices:** | Masimo LNCS Oximetry Sensors, 510(k) No. K041815<br>Masimo LNCS Oximetry Sensors, 510(k) No. K051212<br>Masimo LNCS Oximetry Sensors, 510(k) No. K060143 |

### Device Description

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

There is no change in the sensor design or performance. The only change is that the sensors are to be reprocessed and subjected to ethylene oxide (EO) sterilization, and are to be supplied as sterile sensors by Masimo.

### Predicate Device

The predicate devices used in this filing are the LNCS Oximetry Sensors (K041815, K051212, and K060143).

# 510(k) SUMMARY

### Intended Use/ Indications for Use

The 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.

### Performance Testing

Performance data include results from in-house and laboratory validation testing on the sensors after they have been reprocessed and subjected to EO sterilization.

### Conclusion

The results of the performance data demonstrate that the LNCS Oximetery Sensors, after reprocessed and sterilized are as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 30 2009

Re: K083719
Trade/Device Name: LNCS Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: July 24, 2009
Received: July 29, 2009

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

List of Models

| Masimo Corporation, Models |
|---|
| **LNCS Oximetry Sensors (11)** |
| Adtx |
| Adtx-3 |
| Pdtx |
| Pdtx-3 |
| Inf |
| Inf-3 |
| Neo |
| Neo-3 |
| NeoPt |
| NeoPt-3 |
| NeoPt-500 |

# Indications for Use

510(k) Number (if known): K 083719

Device Name: LNCS Sensors

Indications For Use:

The 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.

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

510(k) Number: K083719

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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)**