SEP 2 0 2004

K 042346

# 510(k) SUMMARY

MASIMO

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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:** | James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance |
| **Date Summary Prepared:** | August 27, 2004 |
| **Trade Name** | LNOPv and LNOP x Oximetry Sensors |
| **Common Name** | Oximeter Sensor |
| **Classification Name and Product Code:** | Oximeter (74DQA) (870.2700)<br>Cable, Transducer and Electrode (74DSA) (870.2900) |
| **Substantially Equivalent Devices:** | Masimo SET® Radical Pulse Oximeter with SatShare™ and LNOP® series of Sensors and Cables<br>510(k) Number - K031330<br>SPO2.COM A, I, P, N, RSI Pulse Oximeter Sensors<br>510(k) Number – K033298 |

**Device Description**

The LNOPx and LNOP x Oximetry Sensors are fully compatible disposable and reusable sensors for use with Masimo SET and Masimo SET compatible pulse oximeter monitors. They represent a design change to the Masimo LNOP Oximetry Sensors.

The LNOPv and LNOP x disposable sensors are similar in construction to the predicate devices except that the SPO2.COM sensors are cable based while the LNOP sensors including the LNOPv and LNOP x sensors are flex circuit based. The emitter and detector are connected to the flex circuit. The sensors have an adhesive bandage to allow the sensor to be attached to the patient's finger or toe. The same emitter (with Red wavelength of 658 nm and Infrared wavelength of 905 nm) is used in Masimo's LNOP series of disposable sensors. Two sizes of disposable LNOPv sensors are available for use with infant and neonatal patients. Two sizes of disposable LNOP x sensors are available for use with adult and pediatric patients. The four sensors are essentially identical except for the emitter and detector spacing and size and orientation of the bandage material. The patient contacting materials in the LNOPv and LNOP x disposable sensors are the same that is used in Masimo's SPO2.COM sensor line. The LNOPv and LNOP x disposable sensors are supplied non-sterile for single patient use.

# 510(k) SUMMARY

**Predicate Devices**

| LNCS Sensor Line | Masimo Predicate LNOP Sensors – in K031330, K033298 |
|---|---|
| LNOP Adtx – Adult Disposable Sensor | LNOP-Adt, SPO2.COM A |
| LNOP Pdtx – Pediatric DisposableSensor | LNOP- Pdt, SPO2.COM P |
| LNOPv In – Infant Disposable Sensor | LNOP-Neo, SPO2.COM I |
| LNOP Ne – Neonatal Disposable Sensor | LNOP-Neo, SPO2.COM N |

**Intended Use**

The LNOPv and LNOP x Oximetry Sensors are intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin ($SpO_2$) and pulse rate (measured by an $SpO_2$ sensor) for adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

**Technology Comparison**

The LNOPv and LNOP x Oximetry Sensors are substantially equivalent in intended use, design, principles of operation, materials, and performance to predicate sensors and operate on identical principles of non-invasive optical assessment of tissue oxygenation using emitters and detectors.

The LNOPv and LNOP x Oximetry Sensors are designed, configured, and manufactured for full compatibility with Masimo SET and Masimo SET compatible pulse oximeters. The LNOPv and LNOP x Oximetry Sensors are constructed of similar materials and components of equivalent specifications as used in the predicate devices.

The accuracy of the LNOPv and LNOP x Oximetry Sensors is equivalent to those of the predicate devices.

**Performance Testing**

Biocompatibility

All the patient contacting materials used in the LNOPv and LNOP x Oximetry Sensors are the same materials that are used in Masimo's SPO2.COM series of sensors. Test results demonstrated that the materials were non-toxic, non-irritating, and non sensitizing.

Environmental Testing

Applicable environmetal testing per the Reviewers Guidance for Premarket Submissions - November 1993, i.e. electrical, mechanical and environmental were performed and all tests passed

Clinical Testing

Clinical studies were performed using the LNOPv and LNOP x Oximetry Sensors on healthy adult volunteer subjects during motion and no motion conditions who were subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter. Clinical testing of the LNOPv and LNOP x Oximetry Sensors resulted in an accuracy of less than 2% $SpO_2$ $A_{RMS}$ in the range of 70%-100% $SaO_2$ for adults, pediatrics and infants and less than 3% $A_{RMS}$ for neonates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2004

Mr. James J. Cronin
Vice President, President, Regulatory Affairs/Quality Assurance
Masimo Corporation
40 Parker
Irvine, California 92618

Re: K042346
Trade/Device Name: LNOPv and LNOP x Oximetry Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 27, 2004
Received: August 30, 2004

Dear Mr. Cronin:

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.

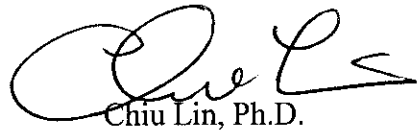
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
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):**

**Device Name:** LNOPv and LNOP x Oximetry Sensors

**Indications For Use:**

The LNOPv and LNOP x Oximetry 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** _____ 0009
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 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

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