FEB - 9 2005

510(k) SUMMARY

K050068

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Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 949-297-7000 FAX 949-297-7001
Company Contact:	James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance
Date Summary Prepared:	February 7, 2005
Trade Name	LNOPv Ad-L and Pd-L Oximetry Sensors
Common Name	Oximeter Sensor
Classification Name and Product Code:	Oximeter (74DQA) (870.2700)
Substantially Equivalent Devices:	LNOPv and LNOP x Oximetry Sensors – K042346

Device Description

The LNOPv Ad-L and Pd-L Oximetry Sensors are fully compatible disposable sensors for use with Masimo SET and Masimo SET compatible pulse oximeter monitors. They represent a design change to the Masimo LNOPv Oximetry Sensors.

The LNOPv Ad-L and Pd-L disposable sensors are similar in construction to the predicate devices LNOPv In and LNOPv Ne except that the LNOPv Ad-L and Pd-L have a shorter tail and the emitter and detector position is switched. The LNOPv Ad-L and Pd-L use the same emitters (with Red wavelength of 658 nm and Infrared wavelength of 905 nm) as used in Masimo's LNOPv In and Ne sensors. The patient contacting materials in the LNOPv Ad-L and Pd-L disposable sensors are the same that is used in Masimo's LNOPv In and Ne sensors. The LNOPv Ad-L and Pd-L disposable sensors are supplied non-sterile for single patient use.

The LNOPv Ad-L and Pd-L disposable sensors have the same electrical, optical, and material components as the LNOPv In and Ne disposable sensors.

Predicate Devices

LNOPv Sensor Line	Masimo Predicate LNOP Sensors – in K04236
LNOPv Ad-L – Adult Disposable Sensor	LNOPv Ne
LNOPv Pd-L – Pediatric Disposable Sensor	LNOPv In

510(k) SUMMARY

Intended Use

The LNOPv Ad-L and Pd-L 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 and , pediatric patients in hospitals, hospital-type facilities, mobile, and home environments.

Technology Comparison

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

The accuracy of the LNOPv Ad-L and Pd-L Oximetry Sensors is equivalent to those of the predicate devices.

Performance Testing

Biocompatibility

All the patient contacting materials used in the LNOPv Ad-L and Pd-L Oximetry Sensors are the same materials that are used in Masimo's LNOPv In and Ne 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 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 Oximetry Disposable sensors resulted in an accuracy of less than 2% SpO_2 A_{RMS} in the range of 70%-100% SaO_2 for adults and pediatrics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K050068
Trade/Device Name: LNOPv Ad-L Oximetry Sensors
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: January 10, 2005
Received: January 12, 2005

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 (240) 276-0120. 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/industry/support/index.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 Ad-L and Pd-L Oximetry Sensors

Indications For Use:

The LNOPv Ad-L and Pd-L 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 and pediatric 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 Subpart D) (Per 21 CFR 807 Subpart C)

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number K050068