K051439

510(k) SUMMARY

JUL 15 2005

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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:	May 23, 2005
Trade Name	LNOP Blue Oximetry Sensors
Common Name	Oximeter Sensor
Classification Name and Product Code:	Oximeter (74DQA) (870.2700)
Substantially Equivalent Devices:	Masimo SET® Rad 57 Pulse CO-Oximeter 510(k) Number - K042536

Device Description

The LNOP Blue Oximetry Sensors are fully compatible disposable sensors for use with Masimo SET and Masimo SET compatible pulse oximeter monitors. The LNOP Blue sensor is substantially equivalent to Masimo's LNOP Inf-L sensor except it is designed for use on patients with congenital cyanotic cardiac lesions.

Intended Use

The LNOP Blue 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 pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

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Technology Comparison

The LNOP Blue oximetry sensors are 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 LNOP Blue oximetry sensors are designed, configured, and manufactured for full compatibility with Masimo SET and Masimo SET compatible pulse oximeters. The LNOP Blue oximetry sensors are constructed of similar materials and components as used in the predicate devices.

Performance Testing

Biocompatibility

All the patient contacting materials used in the LNOP Blue sensors are the same materials that are used in Masimo's LNOP Inf-L sensors. Test results demonstrated that the materials were non-toxic, non-irritating, and non sensitizing.

Clinical Testing

Clinical studies were performed using the LNOP Blue Disposable oximetry sensors with Masimo SET Radical Pulse Oximeters on pediatric, infant, and neonatal patients with congenital cyanotic cardiac lesions 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 LNOP Disposable sensors resulted in an accuracy of less than 4% SpO_2 A_{RMS} in the range of 60%-80% SaO_2 and less than 3% SpO2 ARMS in the range of 80%-100% for pediatrics, infants and neonates on patients with congenital cyanotic lesions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2005

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

Re: K051439
Trade/Device Name: LNOP Blue Oximetry Sensor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximetry Sensor
Regulatory Class: II
Product Code: DQA
Dated: May 31, 2005
Received: June 02, 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: LNOP Blue

Indications For Use:

The LNOP Blue 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 pediatric, infant, and neonatal patients with congenital cyanotic cardiac lesions in hospitals, hospital-type facilities, mobile, and home environments.

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Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(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

510(k) Number: K051439