JUL 12 2005

K05/2/2

510(k) SUMMARY

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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 10, 2005
Trade Name	LNCS Oximetry Sensors
Common Name	Oximeter Sensor
Classification Name and Product Code:	Oximeter (74DQA) (870.2700) Cable, Transducer and Electrode (74DSA) (870.2900) Oximeter, Ear (74DPZ) (870.2710)
Substantially Equivalent Devices:	LNCS Oximetry Sensors 510(k) Number – K041815 SPO2.COM A, P, I, N, RS-I Pulse Oximeter Sensors 510(k) Number – K0332 Nellcor N-395 Pulse Oximeter – K991823 Nellcor N-200 Pulse Oximeter – K863784

Device Description

The LNCS Oximetry Sensors are fully compatible disposable and reusable sensors for use with Masimo SET and Masimo SET compatible pulse oximeter monitors and also with Nellcor and Nellcor compatible pulse oximeter monitors. There is no change in design to the sensors. The only change is to add that the sensors can also be used with Nellcor and Nellcor compatible pulse oximeter monitors.

Intended Use

The LNCS 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.

510(k) SUMMARY

Technology Comparison

The LNCS 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 LNCS oximetry sensors are designed, configured, and manufactured for full compatibility with Masimo SET and Masimo SET compatible pulse oximeters and Nellcor and Nellcor compatible pulse oximeter monitors. The LNCS oximetry sensors are constructed of exact materials and components as used in the predicate devices.

The accuracy of the LNCS oximetry sensors is equivalent to those of the predicate devices.

Performance Testing

Biocompatibility

All the patient contacting materials used in the LNCS sensors are the same materials that are used in Masimo's LNOP 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 LNCS Disposable and Reusable oximetry sensors with Nellcor N-200 instruments on healthy adult volunteer subjects during 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 LNCS Disposable and Reusable 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

JUL 12 2005

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

Re: K051212
Trade/Device Name: Modification to LCN Oximetry Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter Sensor
Regulatory Class: Class II
Product Code: DQA
Dated: June 30, 2005
Received: July 1, 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,

Chin 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: 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.

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: K051212