

JUL 29 2004

510(k) SUMMARY

K041815



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Company Contact: James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance

Date Summary Prepared: July 2, 2004

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: Masimo SET[®] Radical Pulse Oximeter with SatShare[™] and LNOP[®]
series of Sensors and Cables
510(k) Number - K031330
Masimo SET Intellivue Pulse Oximeter Module
510(k) Number – K040259
SPO2.COM A, P, I, N, RS-I Pulse Oximeter Sensors
510(k) Number – K033298

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. They represent a design change to the Masimo LNOP Oximetry Sensors.

The LNCS DC-I/DC-IP reusable sensors are essentially identical to Masimo LNOP-DC-I/DC-IP sensors except for the connector at the end of the cable which interfaces with the LNCS patient cable. The emitter and detector are mounted in opposing halves of the molded clothespin style sensor with contoured pads to maintain contact with the patient's fingers. The same emitter (with Red wavelength of 658 nm and Infrared wavelength of 905 nm) and detector are used in both the LNCS DC-I/DC-IP and LNOP-DC-I/DC-IP sensors. The patient contacting materials in the LNCS DC-I/DC-IP and LNOP-DC-I/DC-IP sensors are the same. The LNCS DC-I/DC-IP sensors are supplied non-sterile.

The LNCS TC-I and TF-I reusable sensors are essentially identical to Masimo LNOP-Ear and TF-I sensors except for the connector at the end of the cable which interfaces with the LNCS patient cable. The same emitter (with Red wavelength of 653/659 nm and Infrared wavelength of 880 nm respectively) and detector are used in

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both the LNCS TC-I and TF-I and LNOP- Ear and TF-I sensors. The patient contacting materials in the LNCS TC-I and TF-I and LNOP- Ear and TF-I sensors are the same. The LNCS TC-I and TF-I sensors are supplied non-sterile.

The LNCS disposable sensors are similar in construction to the predicate devices except that the LNCS sensors are cable based while the LNOP sensors are flex circuit based. The emitter and detector are connected to the cable assembly. 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. Four sizes of disposable LNCS sensors are available for use with adult, pediatric, infant and neonatal 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 LNCS disposable sensors are the same that is used in Masimo's LNOP sensor line. The LNCS disposable sensors are supplied non-sterile for single patient use.

The LNCS patient cables are similar in construction to the predicate device enabling the LNCS Oximetry Sensors to be connected to Masimo and Masimo compatible pulse oximeter monitors.

Predicate Devices

LNCS Sensor Line	Masimo Predicate LNOP Sensors – in K031330, K040259
LNCS DC-I/DC-IP – Reusable Adult/Pediatric Sensors	LNOP-DC-I/DC-IP
LNCS Adt – Adult Disposable Sensor ✓	LNOP-Adt
LNCS Pdt – Pediatric Disposable Sensor ✓	LNOP- Pdt
LNCS Inf – Infant Disposable Sensor ✓	LNOP-Neo
LNCS Neo – Neonatal Disposable Sensor ✓	LNOP-Neo
LNCS NeoPt – Neonatal Disposable Sensor	LNOP NeoPt
LNC 10 - Patient Cable	PC Patient Cable
LNC to PC	N/A
LNC to Intellivue	MP12
LNCS TC-I – Reusable Ear Sensor ✓	LNOP Ear
LNCS TF-I – Reusable Transflectance Sensor ✓	LNOP-TF-I

Intended Use

The LNCS oximetry sensors and cables are intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor) for adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Technology Comparison

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

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

Performance Testing

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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 environmental 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 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 SPO2.COM 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.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James J. Cronin
Vice President, Regulatory Affairs & Quality Assurance
Masimo Corporation
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Re: K041815
Trade/Device Name: LNCS Oximetry Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 2, 2004
Received: July 6, 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: LNCS Sensors and Cables

Indications For Use:

The LNCS Sensors and Cables are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ 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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Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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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