OCT 2 6 2011

510(k) Summary: K111621: Masimo Resposable SpO2 Series Oximetry Sensors

Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 949-297-7000 FAX 949-297-7592
Company Contact:	Anil Bhalani, Director of Regulatory Affairs
Date Summary Prepared:	September 29, 2011
Trade Name:	Masimo ReSposable SpO_2 Series Oximetry Sensors
Common Name:	Oximeter Sensor
Regulation Number:	21 CFR 870.2700
Regulation Name:	Oximeter
Regulation Class:	Class II
Product Code:	DQA
Substantially Equivalent Devices:	K101896, LNCS/M-LNCS Oximetry Sensors K100617, Masimo ReSposable Oximetry Sensors K012992, Masimo SET Radical Pulse Oximeter with Satshare and Masimo Series of Sensors and Cables

Device Description

The Masimo ReSposable SpO_2 Series Oximetry Sensors are pulse oximetry sensors. They measure tissue oxygenation non-invasively through infrared emitters and detectors. The ReSposable SpO_2 Series Oximetry Sensors are fully compatible for use with instruments which include the following technologies:

- Masimo SET technology
- Masimo Rainbow SET technology
- Nellcor technology
- Philips FAST-SpO_2 technology

Predicate Devices

The predicate devices used in this filing are:

1. K100617, Masimo ReSposable Oximetry Sensors
2. K101896, LNCS/M-LNCS Oximetry Sensors
3. K012992, Masimo SET Radical Pulse Oximeter with Satshare and Masimo Series of Sensors and Cables

Intended Use/ Indications for Use

The Masimo ReSposable SpO_2 Series Oximetry Sensors are indicated for the continuous non-invasive 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 motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Comparison to Predicate Devices

Technology Comparison
The Masimo ReSposable SpO_2 Series Oximetry Sensors are substantially equivalent to the predicate sensors in the design, principles of operation, and performance. The Masimo ReSposable SpO_2 Series Oximetry Sensors and the predicates operate on identical principles of non-invasive optical assessment of tissue oxygenation using emitters and detectors.

Indications for Use
The Masimo ReSposable SpO2 Series Oximetry Sensors have identical indications for use as the predicate LNCS/M-LNCS oximetry sensors (K101896). Compared to the predicate Masimo ReSposable Oximetry Sensors (K100617), the Masimo ReSposable SpO2 Series Oximetry Sensors have additional indications for use of infant and neonatal populations. The Masimo ReSposable SpO2 Series Oximetry Sensors' indications are different from the predicate Masimo LNOP YI sensor (K012992). This predicate is indicated for continuous and spot-check monitoring, and for use in infant, pediatric, and adult patient populations. The subject device is indicated only for continuous monitoring and for use in adult, pediatric, infant, and neonatal patient populations.

Physical Characteristics
The reusable portion of the subject device most closely resembles the predicate LNOP YI sensor (K012992). Both devices are bifurcated, with one branch ending in the LED, and the other branch ending in the detector. This design is very different from the reusable portion of the other predicates, which have the LED and detector on a single wire, which wraps around the sensor site.

Clinical and Non-clinical Testing

The following clinical and non-clinical testing was conducted to verify that the Masimo ReSposable SpO_2 Series Oximetry Sensors met all design specifications: Biocompatibility studies, Ambient light rejection, light transmission or light piping, electrocautery noise rejection, environmental noise analysis, pulse rate verification, sensor retention force, insertion and removal force, static pull force, patient access/contact, sensor removal and plastic removal strength, current transfer ratio, sensor skin temperature, moisture resistance and cleaning, sensor water (IPX) and Bleach Test, drop, storage and operating conditions.

Conclusion:

Based on information provided in this premarket notification, we conclude that the Masimo ReSposable SpO2 Series Oximetry Sensors are substantially equivalent to the predicate devices and that the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Anil Bhalani
Director of Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

OCT 2 6 2011

Re: K111621
Trade/Device Name: Masimo ReSposable SpO_2 Series Oximetry Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: October 14, 2011
Received: October 19, 2011

Dear Mr. Bhalani:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known):

Device Name: Masimo ReSposable SpO_2 Series Oximetry Sensors

Indications for Use:

The ReSposable SpO_2 Series is indicated for the continuous non-invasive 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 _____
(Part 21 CFR 801 Subpart D) (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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