FEB 2 4 2012

510(k) Summary K113596

Submitter:	Masimo Corporation 40 Parker Irvine, CA 92618 (949) 297-7000 Fax: (949) 297-7592
Company Contact:	David Collette Senior Manager, Regulatory Affairs
Date Prepared:	January 25, 2012
Trade Name:	Masimo SET® Reusable Soft Oximetry Sensors
Regulation Number:	21 CFR 870.2700
Regulation Name:	Pulse Oximeter (Oximetry Sensors)
Regulatory Class:	Class II
Product Code	DQA
Cleared Device:	K090662 – Masimo SET Reusable Soft Oximetry Sensors

Device Description

The Masimo SET Reusable Soft Oximetry Sensors (DBI/P Sensors) have been cleared under K090662 for use with Masimo SET and Masimo SET -compatible pulse oximeter monitors as well as Nellcor and Nellcor compatible pulse oximeter monitors. This submission presents data demonstrating that the DBI/P Sensors also are compatible for use with pulse oximeter monitors incorporating Philips FAST SpO_2 Technology. Two additional M-LNCS sensors with M-15 connectors are included in this notification.

Indications for Use

The Masimo SET Reusable Soft Sensors are indicated for the continuous noninvasive monitoring and spot-checking 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 no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Comparative Analysis

There are no changes to the design of the device cleared in K090662. Specifically, the principles of operation performance and materials of the device remain unchanged from the existing Masimo SET Reusable Soft Oximetry Sensors.

Validation Testing

Bench and clinical testing of the Masimo SET Reusable Soft Oximetry Sensors was performed using monitors incorporating Philips FAST SpO_2 Technology and the results demonstrate that the SpO_2 and pulse rate accuracy is equivalent to the performance data submitted for the previously cleared Masimo sensors.

Conclusion

Data presented in this submission demonstrate that, when used with pulse oximetry monitors incorporating the Philips FAST Technology, the Masimo SET Reusable Soft Oximetry Sensors are substantially equivalent to the cleared device.

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. David Collette
Senior Manager, Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

FEB 24 2012

Re: K113596
Trade/Device Name: Masimo SET® Reusable Soft Oximetry Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: January 25, 2012
Received: January 26, 2012

Dear Mr. Collette:

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

Indications for Use

510(k) Number: K113596

Device Name: Masimo SET® Reusable Soft Oximetry Sensors

Indications for Use:

The Masimo SET Reusable Soft Sensors are indicated for the continuous noninvasive monitoring and spot-checking 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 no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schuttin

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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