AUG 10 2009

510(k) SUMMARY

K090662

Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 949-297-7000 FAX 949-297-7001
Company Contact:	Marguerite Thomlinson, Manager of Regulatory Affairs
Date Summary Prepared:	March 9, 2009
Trade Name	Masimo SET Reusable Soft Oximetry Sensors
Common Name	Oximeter Sensor
Classification Name and Product Code:	Oximeter (74DQA) (870.2700) Cable, Transducer and Electrode (74DSA) (870.2900)
Substantially Equivalent Devices:	Masimo LNCS Oximetry Sensors , 510(k) No. K051212

Device Description

The Masimo SET Reusable Soft Oximetry Sensors (DBI/P Sensors) are fully compatible reusable sensors for use with Masimo SET and Masimo SET compatible pulse oximeter monitors. The DBI/P Sensors are also fully compatible for use with Masimo Rainbow SET and Masimo Rainbow SET compatible pulse CO-oximeter monitors. Additionally, the DBI Sensors are also compatible with Nellcor and Nellcor compatible pulse oximeter monitors.

Predicate Device

The predicate devices used in this filing are the Masimo LNCS Oximetry Sensors (K051212).

Intended Use

The Masimo SET Reusable Soft Sensors are indicated for the continuous noninvasive monitoring and spotchecking 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.

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Technology

The DBI/P Sensors are substantially equivalent in design, principles of operation, materials, and performance to predicate device LNCS Oximetry Sensors. The DBI/P Sensor performance is equivalent to those of the LNCS Oximetry Sensor.

The specifications for the DBI/P Sensors for adults (> 30 kg) and pediatrics (10-50 kg) are the following:

FEATURES	SENSOR SPECIFICATIONS: with Masimo SET and Masimo Rainbow SET Technology	SENSOR SPECIFICATIONS: with Nellcor and Nellcor Compatible Technology
Accuracy – SpO_2 During No Motion Conditions	Adults, Pediatrics: 70% - 100% ± 2% Adults, Pediatrics: 0% - 69% unspecified	Adults, Pediatrics: 70% - 100% ± 2% Adults, Pediatrics: 0% - 69% unspecified
Accuracy – SpO_2 Low Perfusion	Adults, Pediatrics: 70% - 100% ± 2% Adults, Pediatrics: 0% - 69% unspecified	N/A
Accuracy – Pulse Rate During No Motion Conditions	Adults, Pediatrics: 25 - 240 ± 3 bpm	Adults, Pediatrics: 25 - 240 ± 3 bpm
Accuracy – Pulse Rate Low Perfusion	Adults, Pediatrics: 25 - 240 ± 3 bpm	N/A

Test Summary

The DBI/P Sensors comply with the voluntary standards as detailed in this submission. The following quality assurance measures were applied to the development of the DBI/P Sensors:

- Risk Analysis
- Design Reviews
- Biocompatibility Testing
- Performance Testing
- Safety Testing
- Environmental Testing
- Clinical Testing

Conclusions

The information in this 510(k) submission demonstrates that the Masimo SET® Reusable Soft Oximetry Sensors are substantially equivalent to the predicate device, with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Marguerite Thomlinson
Manager of Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

AUG 10 2009

Re: K090662
Trade/Device Name: Masimo SET Reusable Soft Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 29, 2009
Received: August 4, 2009

Dear Ms. Thomlinson:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division 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: Masimo SET Reusable Soft Sensors

Indications For Use:

The Masimo SET Reusable Soft Sensors are indicated for the continuous noninvasive monitoring and spotchecking 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.

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

510(k) Number: K090662

Prescription Use _____X_____ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109 Subpart D) (Per 21 CFR 801.109 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)