510(k) SUMMARY

K101031
NOV 18 2010

Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 949-297-7000 FAX 949-297-7592
Company Contact:	Shelly Harris, Manager of Regulatory Affairs
Date Summary Prepared:	November 5, 2010
Trade Name:	Masimo Resposable Oximetry Sensors
Common Name:	Oximeter Sensor
Regulation Number:	21 CFR 870.2700
Regulation Name:	Oximeter
Regulation Class:	Class II
Product Code:	DQA, DPZ, DSA
Substantially Equivalent Devices:	Masimo Reusable Ear Sensor, 510(k) No. 012992 LNCS Oximetry Sensors, 510(k) No. K051212

Device Description

The Masimo Disposable Ear Oximetry Sensors (E1 Sensors) are fully compatible for use with instruments which include or compatible with the following technologies:

- Masimo SET technology
- Masimo Rainbow SET technology

The E1 Sensors and the predicates (K012992) Masimo Reuseable Ear Sensor (LNOP Sensor) and (K051212) the LNCS Reusable Ear Sensor (LNCS Sensor) have similar indications for use/ intended use. The main difference is that the E1 Sensors are disposable ear sensors.

Predicate Device

The predicate devices used in this filing are:

- Masimo Reusable Ear Sensor, 510(k) No. 012992
- LNCS Oximetry Sensors, 510(k) No. K051212

Intended Use/ Indications for Use

The Masimo Disposable Ear Sensors are indicated for single patient use for 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 and pediatric patients, (weighing >30kg), who are well or poorly perfused, in hospitals, hospital-type facilities, mobile, and home environments.

510(k) SUMMARY

Technology Comparison

The E1 Sensors are substantially equivalent to the predicate sensors in the design, principles of operation, and performance. The E1 Sensors and the predicates operate on identical principles of non-invasive optical assessment of tissue oxygenation using emitters and detectors.

Specifications

The specifications for the E1 Sensors are as following:

Masimo SET Technology and Masimo Rainbow SET Technology (Adults and Pediatrics > 30kg)		
Measurement	**Accuracy Range**	**Accuracy**
Arterial Oxygen Saturation (SpO_2), No Motion	70-100%	± 3.5%
Arterial Oxygen Saturation (SpO_2), Low Perfusion	70-100%	± 3.5%
Pulse Rate, No Motion	25-240 bpm	± 3 bpm
Pulse Rate, Low Perfusion	25-240 bpm	± 3 bpm

The E1 Sensors have been validated to the Masimo SET Technology.

Test Summary

The E1 Sensors comply with the voluntary standards as detailed in this submission. The following quality assurance measures were applied to the development of the E1 Sensors:

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

Conclusions

The information in this 510(k) submission demonstrates that the E1 Sensors are substantially equivalent to the predicate devices, with respect to safety, effectiveness, and performance.

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

Ms. Shelly Harris
Manager of Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

NOV 18 2010

Re: K101031
Trade/Device Name: Masimo Disposable Oximetry Ear Sensors
Regulation Number: 21 CFR 870.2710
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DPZ, DSA
Dated: November 5, 2010
Received: November 10, 2010

Dear Ms. Harris:

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 (if known): K101031

NOV 18 2010

Device Name: Masimo Disposable Oximetry Ear Sensors

Indications For Use:

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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)

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

510(k) Number: K101031