510(k) Summary: K120657

SEP 19 2012

Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Contact	Patricia Milbank Vice President, Regulatory Affairs
Date Summary Prepared	September 14, 2012
Trade Name	Masimo SET® Rad 5 Pulse Oximeter Masimo SET® Rad 5v Pulse Oximeter Masimo SET® Rad-8 Pulse Oximeter Masimo rainbow SET® Rad 57 Pulse CO-Oximeter Masimo rainbow SET® Radical 7 Pulse CO-Oximeter Masimo rainbow SET® Rad 87 Pulse CO-Oximeter Masimo LNOP Oximetry Sensors Masimo LNCS/M-LNCS Oximetry Sensors Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors Masimo LNOP/M-LNCS/LNCS Y-I Oximetry Sensors Masimo ReSposable SpO_2 Series Oximetry Sensors
Common Name	Pulse Oximeter and Oximeter Sensor
Regulation Number/Class	21 CFR 870.2700 / Class II
Product Code	DQA
Substantially Equivalent Devices:	Masimo SET Rad 5 Pulse Oximeter (K033296) Masimo SET Rad 5v Pulse Oximeter (K040214) Masimo SET Rad 8 Pulse Oximeter (K092838) Masimo rainbow SET® Rad 57 Pulse CO-Oximeter (K080238) Masimo rainbow SET® Radical 7 Pulse CO-Oximeter (K110280 Masimo rainbow SET® Rad 87 Pulse CO-Oximeter (K091241) Masimo LNOP Oximetry Sensors (K111888) Masimo LNCS/M-LNCS Oximetry Sensors (K051212 and K101896) Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors (K111888) Masimo LNOP/M-LNCS/LNCS Y-I Oximetry Sensors (K012992) Masimo ReSposable SpO_2 Series Oximetry Sensors (K111621)

Description of the Device

Masimo SET® and Masimo rainbow SET® Pulse Oximeter instruments and sensors provide noninvasive monitoring of arterial oxygen saturation (SpO_2) and pulse rate (PR). The Masimo rainbow SET technology also provides noninvasive monitoring of carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (g/dl SpHb), and/or respiration rate (RRa).

This 510(k) is being submitted to support modifications to the device labeling to incorporate the results of clinical trials described in peer-reviewed publications regarding the use of Masimo pulse oximeters and sensors intended to screen newborn patients for critical congenital heart disease (CCHD). These modifications include the published newborn screening protocol for CCHD recommended by a work group selected by SACHDNC, AAP, ACCF and AHA (the "CCHD Workgroup"),[2] and instructions regarding proper use of the subject Masimo devices to implement this protocol.

These labeling changes are being made in direct response to action taken by HHS in September 2011 adding pulse oximeter screening of newborns for CCHD to the Federal Recommended Uniform Screening Panel (RUSP) Guidelines.[1] These guidelines recommend use of devices that a) are motion-tolerant, b) report functional oxygen saturation, c) have been validated in low perfusion conditions; and d) have been cleared by the FDA for use in newborns, criteria that are fully met by the subject Masimo devices.

Clinical Summary

In reaching their recommendations, the CCHD Workgroup relied upon two independent prospective clinical studies finding "...sufficient evidence to begin screening for low blood oxygen saturation through the use of pulse-oximetry monitoring to detect CCHD in well-infant and intermediate care nurseries."[1]

In both of these studies, the investigators selected the Masimo SET technology[3] and the Masimo rainbow SET technology[4] for newborn screening as follows:

- A prospective clinical study of 39,821 newborn subjects at 5 maternity centers in Sweden using the Masimo Radical pulse oximeter.[3] The Masimo Rad 5, Rad 5v and Rad 8 systems incorporate the same Masimo SET technology used in this study.

- A prospective clinical study of 20,055 newborn subjects at 6 maternity centers in the UK using the Masimo Radical 7 pulse CO-Oximeter.[4] The Masimo Rad 57 and Rad 87 systems incorporate the same Masimo rainbow SET technology used in this study.

Non-Clinical Summary

No non-clinical studies were required to support the proposed changes to the labeling regarding the use of the Masimo SET and Masimo rainbow SET technologies to perform screening of newborn subjects for CCHD. The Masimo pulse oximeter devices comply with the requirements

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

SEP 19 2012

Masimo Corporation
c/o Patricia Milbank, JD
Vice President, Regulatory Affairs
40 Parker
Irvine, CA 92618

Re: K120657
Trade/Device Name: Masimo SET and Masimo rainbow SET Pulse Oximeters and Sensors
Regulation Number: 21 CFR §870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 14, 2012
Received: September 17, 2012

Dear Ms. Milbank:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120657

Device Name: Masimo SET® Rad 5 Pulse Oximeter

Indications for Use:

The Masimo Rad 5 Pulse Oximeter is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo Rad 5 Pulse Oximeter is indicated for use with adult, pediatric, 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___ (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)

(Division Sign-Off)
Division of Cardiovascular Devices
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Indications for Use

510(k) Number: K120657

Device Name: Masimo SET® Rad 5v Pulse Oximeter

Indications for Use:

The Masimo Rad 5v Pulse Oximeter is indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo Rad 5v Pulse Oximeter is indicated for use with adult, pediatric, 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number: K120657

Device Name: Masimo SET® Rad 8 Pulse Oximeter

Indications for Use:

The Masimo Rad 8 Pulse Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo Rainbow Rad 8 Pulse Oximeter and accessories are indicated for use with adult, pediatric, 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Indications for Use

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Indications for Use

510(k) Number: K120657

Device Name: Masimo Rainbow SET® Rad 57 Pulse CO-Oximeter

Indications for Use:

The Masimo Rad 57 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). The Masimo Rad 57 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number: K120657

Device Name: Masimo rainbow SET® Radical 7 Pulse CO-Oximeter

Indications for Use:

The Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, 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. In addition, the Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical 7 Pulse CO-Oximeter end accessories of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate to multi-parameter devices for the display of those devices.

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

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Indications for Use

510(k) Number: K120657

Device Name: Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter

Indications for Use:

The Masimo Rad 87 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RR). The Masimo Rad 87 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number K120657

Indications for Use

510(k) Number: K120657

Device Name: Masimo LNOP Oximetry Sensors

Indications for Use:

The Masimo LNOP Oximetry Sensors are indicated for the continuous noninvasive 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number: K120657

Device Name: Masimo LNCS/M-LNCS Oximetry Sensors

Indications for Use:

The Masimo LNCS/M-LNCS Oximetry Sensors are indicated for the continuous noninvasive 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) Number K120657

Indications for Use

510(k) Number: K120657

Device Name: Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors

Indications for Use:

The Masimo LNOP/M-LNCS/LNCS Multisite-L Oximetry Sensors are indicated for the continuous noninvasive 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.

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Indications for Use

510(k) Number: K120657

Device Name: Masimo LNOP/M-LNCS/LNCS Y-I Oximetry Sensors

Indications for Use:

The Masimo LNOP/M-LNCS/LNCS Y-I Oximetry Sensors are indicated for the continuous noninvasive 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.

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Indications for Use

510(k) Number: K120657

Device Name: Masimo ReSposable SpO_2 Series Oximetry Sensors

Indications for Use:

The Masimo ReSposable SpO_2 Series Oximetry Sensors are indicated for the continuous noninvasive 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.

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