

510(k) SUMMARY

Submitted by: Masimo Corporation
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Company Contact: Marguerite Thomlinson, Manager of Regulatory Affairs

Date Summary Prepared: July 7, 2009

Trade Name Rainbow Resposable Pulse CO-Oximeter Sensors

Common Name Oximeter Sensor

Classification Name and Product Code: Oximeter (74DQA) (870.2700)
Cable, Transducer and Electrode (74DSA) (870.2900)

Substantially Equivalent Devices: Rainbow Adhesive CO-Oximetry Sensors, 510(k) Number K081659

Device Description

The Rainbow Resposable Sensors are fully compatible sensors for use with Masimo Rainbow SET and Masimo Rainbow SET compatible pulse CO-Oximeter monitors. They represent a design change to the Masimo Rainbow Adhesive Sensors in the K0801659 filing.

The Rainbow Resposable Sensors have the similar intended use/indications for use and performance specifications as the Rainbow Adhesive Sensors in the K0801659 filing. The main difference is that the entire Rainbow Adhesive Sensor is single-patient use. However for the Rainbow Resposable Sensor, the tape assembly is single-patient use and the emitter/detector/cable assembly is detachable from the tape assembly. This emitter/detector/cable assembly is reusable. Also, the Rainbow Resposable Sensors are not indicated for the measurement of carboxyhemoglobin saturation and motion conditions.

Predicate Devices

The predicate devices for this filing are the Rainbow Adhesive Pulse CO-Oximetry Sensors (K081659).

Intended Use/ Indications for Use

The Rainbow Resposable Sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂), pulse rate, methemoglobin saturation (SpMet), and/or total hemoglobin (SpHb). The Rainbow Resposable Sensors are indicated 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 Comparison

The Rainbow Resposable Sensors are substantially equivalent in intended use, design, principles of operation, materials, and performance to predicate sensors and operate on identical principles of non-invasive optical assessment of tissue oxygenation using emitters and detectors.

They are designed, configured, and manufactured for full compatibility with Masimo Rainbow SET and Masimo Rainbow SET compatible pulse CO-Oximeters. The Rainbow Resposable Sensors are constructed of similar materials and components of equivalent specifications as used in the predicate devices, with accuracy that is also equivalent to those of the predicate devices.

Performance Testing

Biocompatibility

Test results of all patient-contact materials used in the Rainbow Resposable Sensors demonstrated that the materials were non-toxic, non-irritating, and non-sensitizing.

Environmental

Applicable environmental testing per the Reviewers Guidance for Premarket Submissions – November 1993, i.e. electrical, mechanical and environmental were performed and all tests passed.

Clinical

Clinical studies for the Rainbow Resposable Sensors are similar to those of the Rainbow Adhesive Sensors, resulting in the following sensor specifications for adult and pediatric patients:

Measurement	Accuracy Range	Accuracy
Arterial Oxygen Saturation (SpO ₂), No Motion	60-80%	+ 3%
Arterial Oxygen Saturation (SpO ₂), No Motion	70-100%	+ 2%
Arterial Oxygen Saturation (SpO ₂), Low Perfusion	70-100%	+ 2%
Pulse Rate, No Motion	25-240 bpm	+ 3 bpm
Pulse Rate, Low Perfusion	25-240 bpm	+ 3 bpm
Methemoglobin (SpMet), No Motion	1-15%	+ 1%
Total Hemoglobin Concentration (SpHb), No Motion	8-17 g/dL	+ 1 g/dL



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K090165
Trade/Device Name: Rainbow Resposable Pulse CO-Oximeter Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DSA, JKS
Dated: March 31, 2009
Received: April 6, 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,



Susan Runner, D.D.S., M.A.

Acting 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):

K090165

Device Name: Rainbow Resposable Pulse CO-Oximeter Sensors

Indications For Use:

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Prescription Use X
(Per 21 CFR 801.109 Subpart D)

AND/OR

Over-The-Counter Use _____
(Per 21 CFR 801.109 Subpart C)

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

J. Schmitt Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090165