K081659

510(k) SUMMARY

SEP 09 2008

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:	June 9, 2008
Trade Name	Rainbow Adhesive Pulse CO-Oximeter Sensors
Common Name	Oximeter Sensor
Classification Name and Product Code:	Oximeter (74DQA) (870.2700) Cable, Transducer and Electrode (74DSA) (870.2900) Carbon Monoxide Test System (JKS) (862.3220)
Substantially Equivalent Devices:	Masimo Rainbow SET Radical 7/ Rad 87/ Rad 57t Pulse CO-Oximeters and Accessories, 510(k) Number K080238 Masimo Rainbow Adhesive CO-Oximetry Sensors, 510(k) Number K071024

Device Description

The Rainbow Adhesive Sensors are fully compatible disposable sensor for use with Masimo Rainbow SET and Masimo Rainbow SET compatible pulse CO-Oximeter monitors. They represent a design change to the Masimo Rainbow DCI and Direct Connect (Reusable) Sensors in the K080238 filing and the Rainbow Adhesive CO-Oximetry Sensors in the K071024 filing.

The Rainbow Adhesive Sensors in this filing have the same intended use/indications for use and performance specifications as the Rainbow Reusable Sensors in the K080238 filing. However, The Rainbow Adhesive Sensors in this filing are similar in construction to the Rainbow Adhesive CO-Oximetry Sensors in the K071024 filing. The main difference is that the sensors in the K071024 filing have 8-wavelengths and the sensors in this filing have 12-wavelengths.

Similar to the 8-wavelength sensors, the sensors in this filing include the emitter and detector assemblies connecting to the flex circuit, and an adhesive bandage to allow the sensor to be attached to the patient's finger, hand, foot or toe. Sensor sizing for use with adult, pediatric, infant, and neonatal patients are the

same for the sensors in the K071024 and for the sensors in this filing. The patient-contact materials in the Rainbow Adhesive Sensors in this filing are the same that is used in the K071024 filing. Also similar to the sensors in the K071024 filing, the Rainbow Adhesive Sensors in this filing are supplied non-sterile for single patient use.

Predicate Devices

Rainbow DCI and Direct Connect Pulse CO-Oximetry Sensors (K080238) and Rainbow Adhesive CO-Oximetry Sensors (K071024).

Intended Use

The Rainbow Adhesive Sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and/or total hemoglobin (SpHb). The Rainbow Adhesive Sensors 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.

Technology Comparison

The Rainbow Adhesive 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.

The Rainbow Adhesive Sensors are designed, configured, and manufactured for full compatibility with Masimo Rainbow SET and Masimo Rainbow SET compatible pulse CO-Oximeters. The Rainbow Adhesive Sensors are constructed of similar materials and components of equivalent specifications as used in the predicate devices.

The accuracy of the Rainbow Adhesive Sensors is equivalent to those of the predicate devices.

Performance Testing

Biocompatibility

Test results of all patient-contact materials used in the Rainbow Adhesive 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 were performed using Masimo Rainbow SET technology with Rainbow Adhesive Sensors on healthy adult volunteer subjects during motion and no motion conditions who were

subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a laboratory CO-Oximeter.

Clinical testing of the Rainbow Adhesive sensors resulted in an accuracy of less than 2% SpO_2 A_{RMS} in the range of 70%-100% SaO_2 and less than 3% SpO_2 A_{RMS} in the range of 60%-80% SaO_2 for adults, pediatrics, and infants.

The Masimo Rainbow SET technology with Rainbow Adhesive Sensors have been validated in human blood studies on adult volunteers against a laboratory CO-Oximeter from 1-40% for carboxyhemoglobin, 1-15% for methemoglobin, and 8-17 g/dL for total hemoglobin. Clinical testing of the Rainbow Adhesive sensors resulted in an accuracy of less than 3% SpCO A_{RMS} in the range of 1%-40% SaCO, an accuracy of less than 1% SpMet A_{RMS} in the range of 1%-15% SaMet, and an accuracy of less than 1 g/dL SpHb A_{RMS} in the range of 8-17 g/dL tHb.

Additional clinical studies were performed using Masimo Rainbow SET technology with Rainbow Adhesive Sensors on hospitalized neonatal patients resulted in an accuracy of less than 3% SpO_2 A_{RMS} in the range of 70%-100% SaO_2 and less than 1% SpMet A_{RMS} in the range of 0% - 2.5% SaMet.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 09 2008

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

Re: K081659
Trade/Device Name: Rainbow Adhesive Pulse CO-Oximeter Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, JKS, DPZ
Dated: August 28, 2008
Received: September 2, 2008

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 such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Chiu Lin, Ph.D.
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: Rainbow Adhesive Pulse CO-Oximeter Sensors

Indications For Use:

The Rainbow Adhesive Sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), and/or total hemoglobin (SpHb). The Rainbow Adhesive Sensors 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.

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

510(k) Number: K081659

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)