K990966

JUN 7 1999

Section 1 — Executive Summary

Masimo SET® 2000 Pulse Oximeter

510(k) Summary

Submitted By:	Masimo Corporation 2852 Kelvin Ave Irvine, CA 92614-5826 (949) 250-9688 FAX (949) 250-9686
Contact:	James J. Cronin Vice President, Regulatory Affairs/Quality Assurance
Trade Name:	Masimo SET® 2000 Pulse Oximeter and accessories
Common/Classification Name:	Oximeter (74DQA) Transducer and Electrode Cable (including connector) (74DSA)
Substantially Equivalent Devices:	Masimo SET MS-1P Pulse Oximeter and accessories 510(k) Number - K973887

Reason for Submission

Premarket notification for Masimo SET® 2000 Pulse Oximeter and accessories, a New Device, seeking authority to market the device under Section 510(k) as a device that is substantially equivalent to the Masimo SET® MS-1P Pulse Oximeter and accessories

Intended Use of Device

The Masimo SET® 2000 Pulse Oximeter and accessories is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Indications for Use

The Masimo SET® 2000 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 SET® 2000 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.

Contraindications For Use:

The Masimo SET® 2000 Pulse Oximeter and accessories are contraindicated for use as apnea monitors.

The Masimo LNOP® Series of Disposable Sensors are contraindicated for patients that exhibit allergic reactions to adhesive tape. The sensors must be removed and repositioned every eight (8) hours and if indicated by circulatory condition or skin integrity reapplied to a different monitoring site.

The Masimo LNOP® Reusable sensor is contraindicated for use for prolonged periods of use. It is not intended for long-term monitoring. It must be removed and repositioned every 4 hours and if indicated by circulatory condition or skin integrity reapplied to a different monitoring site.

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Device Description

The Masimo SET® 2000 pulse oximeter and accessories is a portable stand alone device, connecting cable, and oximetry sensors to nonivasively calculate the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate.

The monitor consists of a screen that displays the pulse plethysmographic waveform, the pulse rate, SpO_2 value, the high and low SpO_2 and pulse rate alarm limits, alarms, trends and status messages.

The monitor contains the electronic hardware and software that receives and calculates the signals from the LED's to determine the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate and provides for the connection to the connecting cable.

The PC series connecting cables connects the monitor to the oximetry sensors and transfers LED drive power and the calibration drive to the oximetry sensors from the monitor and the monitor receives the detector signal from the oximetry sensor.

The LNOP® series of oximetry sensors measure the light absorption of blood from two light emitting diodes (LED's). Oxygen saturated blood absorbs light differently as compared to unsaturated blood. The amount of light absorbed by the blood is used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood.

Configurations

The Masimo SET® 2000 pulse oximeter is available in one configuration as a portable stand alone pulse oximeter that is 4.26 inches high, 9.75 inches wide, 9.75 inches deep, and weighs 6.5 lbs. The unit is powered either with a voltage input of 100-230 Vac, 47 – 63 Hz or with a sealed gel cell battery with an operating time of 2 hours and a charge time of less 8 hours.

The PC series of connecting cables is available in one configuration and three lengths, 4 feet, 8 feet and 12 feet.

The LNOP® series of oximetry sensors is available in five configurations: a single use oximetry sensor intended for adults and pediatrics greater than 30 kg; a single use oximetry sensor intended for pediatrics and small adults greater than 10 kg and less than 50 kg, a single use oximetry sensor intended for neonates less than 10 kg with good skin integrity; a single use oximetry sensor intended for neonates with poor skin integrity less than 1 Kg; and a reusable oximetry sensor intended for adults and pediatrics greater than 30 kg.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 1999

Mr. James J. Cronin
Masimo Corporation
2852 Kelvin Avenue
Irvine, CA 92614-5826

Re: K990966
Masimo SET® 2000 Pulse Oximeter and Assessories
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: March 22, 1999
Received: March 23, 1999

Dear Mr. Cronin:

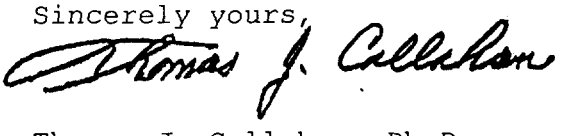
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3 — Indications for Use

510(k) Number (if known): K990966

WARNINGS

Explosion hazard. Do not use the Masimo SET® 2000 Pulse Oximeter in the presence of flammable anesthetics.

A pulse oximeter should NOT be used as an apnea monitor.

A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

If an alarm condition occurs while the alarm silence period is set to off, only alarm indications will be visual displays and symbols related to the alarm condition.

The Masimo SET® 2000 Pulse Oximeter is to be operated by qualified personnel only.

Electric shock hazard. Covers to be removed only by technically qualified service personnel. There are no user-serviceable parts.

To ensure patient electrical isolation, connect only to other equipment with electronically isolated circuits.

Note: Do not connect to an electrical outlet controlled by a wall switch.

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

Do not place the monitor or external power supply in any position that might cause it to fall on the patient. Do not lift the monitor by the power supply cord or patient cable, use only the handle on the monitor.

Do not use the Masimo SET® 2000 Pulse Oximeter or Masimo LNOP® series of sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The Masimo SET® 2000 Pulse Oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.

Interfering Substances: Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia A. Carlson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990966

Prescription Use ✓ **or** **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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