

K 993555

NOV 19 1999

**MASIMO®**

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18 October 1999

**Subject:s** 510(k) Summary of Safety and Effectiveness Information for the Masimo SET®/Quartz 2500 Pulse Oximeter Accessories  
**Proprietary:** Masimo SET®/Quartz 2500 Pulse Oximeter and Accessories  
**Common:** Oximeter  
**Classification:** Oximeter Class II - 21CFR870.2700 - 74 DQA

The 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

The Masimo SET®/Quartz 2500 Pulse Oximeter and Accessories is substantially equivalent to the following currently marketed device(s):

- Masimo SET® 2000 Pulse Oximeter and Accessories

The Masimo SET®/Quartz 2500 Pulse Oximeter and Accessories is a portable stand alone device, connecting cable, and oximetry sensors to noninvasively calculate the functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate.

The monitor consists of a screen that displays the pulse plethysmographic waveform, the pulse rate, SpO<sub>2</sub> value, the high and low SpO<sub>2</sub> and pulse rate alarm limits, alarms, trends and status messages. It 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<sub>2</sub>) and pulse rate and provide for the connection to the connecting cable.

The Masimo SET®/Quartz 2500 Pulse Oximeter is available in one configuration as a portable stand alone pulse oximeter that is 10cm high, 27.5cm wide, 25cm deep and weighs 4 kg. The unit is powered either with a voltage input of 100-240 Vac, 50-60 Hz or with a sealed lead-acid battery with an operating time of 5.5 hours and a charge time of 4.5 hours to 80% capacity.

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

The LNOP<sup>®</sup> 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.

The LNOP<sup>®</sup> 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 with good skin integrity less than 10kg;
- a single use oximetry sensor intended for neonates with poor skin integrity less than 1kg; and
- a reusable oximetry sensor intended for adults and pediatrics greater than 30kg.

The Masimo SET<sup>®</sup>/Quartz 2500 Pulse Oximeter is designed to comply with the following standards:

1. CSA C22.2 #601
2. IEC 601-1, Part 1 and Amendments 1 and 2
3. IEC 601-1-1, Part 1
4. IEC 601-1-2, Part 1
5. IEC 601-1-4, Part 1
6. ISO 9919: 1992
7. EN 865: 1997
8. UL 2601-1

The Masimo SET<sup>®</sup> 2000 Pulse Oximeter and the Masimo SET<sup>®</sup>/Quartz 2500 Pulse Oximeter are substantially equivalent in design concepts, technologies and materials. The Masimo SET<sup>®</sup>/Quartz 2500 Pulse Oximeter was validated through rigorous testing that, in part, support the compliance of the Masimo SET<sup>®</sup>/Quartz 2500 Pulse Oximeter to the above mentioned standards. Additionally, the software for the Masimo SET<sup>®</sup>/Quartz 2500 Pulse Oximeter was developed following a robust software development process and was fully specified and validated by Masimo and Quartz.

The Masimo SET<sup>®</sup>/Quartz 2500 Pulse Oximeter and Accessories is the next generation in the Masimo Pulse Oximeter family of products.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K993555  
Masimo SET®/Quartz 2500 Pulse Oximeter  
Regulatory Class: II (two)  
Product Code: 74 DQA  
Dated: October 18, 1999  
Received: October 20, 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.

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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,

*Chale (H)*

*for*

Celia M. Witten, Ph.D., M.D.  
Acting Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K993555

Device Name: Masimo SET®/Quartz 2500 Pulse Oximeter

Indications for Use:

The Masimo SET®/Quartz 2500 Pulse Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation or arterial hemoglobin (SpO<sub>2</sub>) and pulse rate (measured by an SpO<sub>2</sub> sensor). The Masimo SET®/Quartz 2500 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, and home environments.

The Masimo LNOP® Series of Sensors are indicated for the Masimo SET®/Quartz 2500 Pulse Oximeter and the following:

- A single use oximetry sensor intended for adults and pediatrics greater than 30kg.
- 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 with good skin integrity less than 10kg;
- A single use oximetry sensor intended for neonates with poor skin integrity less than 1kg; and
- A reusable oximetry sensor intended for adults and pediatrics greater than 30kg.

The Masimo PC Series of Patient Cables are indicated for use with the Masimo LNOP® Series of Sensors and the Masimo SET®/Quartz 2500 Pulse Oximeter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Char Adams for JKH*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory, and  
Neurological Devices

510(k) Number: \_\_\_\_\_

Prescription Use  
(Per 21CFR801.109)

X

OR Over-The-Counter Use \_\_\_\_\_