K040259

510(k) SUMMARY

APR 2 2 2004

Submitted by:	Masimo Corporation 2852 Kelvin Ave Irvine, CA 92614-5826 (714) 250-9688 FAX (714) 250-9686
Company Contact:	James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance
Date Summary Prepared:	February 2, 2004
Trade Name	Masimo SET® Intellivue Pulse Oximeter Module
Common Name	Pulse Oximeter
Classification Name	Oximeter (74DQA) (870.2700)
Substantially Equivalent Devices	Masimo SET Radical Pulse Oximeter with SatShare™ and LNOP series of Sensors and Cables 510(k) Number - K031330 Philips Medizin Systeme MP40, MP50, MP60, MP70 and MP90 Intellivue Patie Monitor – K032858

The Masimo SET® IntelliVue Pulse Oximeter Module is a continuous noninvasive, arterial oxygen saturation and pulse rate monitor. The Masimo SET Intellivue Module features Masimo SET algorithms in a Philips single-width Intellivue compatible module.

The following list outlines the key features and benefits of the Masimo SET IntelliVue Module

Features and Benefits

- Clinically proven Masimo SET™ technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- SpO_2, pulse rate, alarm, and signal quality displays
- Compatible with Philips IntelliVue models MP 40/50, MP 60/70 and MP90 – MP 60/70 and MP90 must be equipped with Philips Intellivue Flexible Module Server (FMS) with at least one available module slot.
- Compatible with all Masimo LNOP SpO2 sensors (except LNOP DCSC)

Intended use

The Masimo SET® IntelliVue Pulse Oximeter Module is intended for the 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 and hospital-type facilities.

510(k) SUMMARY

Indications for use

The IntelliVue Pulse Oximeter Module 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 Intellivue Pulse Oximeter Module is indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

Principles of Operation

The principles of operation of the Masimo SET® Intellivue pulse oximeter Module are that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography), and that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by the blood is related to hemoglobin oxygen saturation. The Masimo SET® Intellivue pulse oximeter module decomposes the red and infrared pulsatile absorbance signal into an arterial signal plus a noise component and calculates the ratio of the arterial signals without noise. The ratio of the two arterial pulse-added absorbance signals and its value is used to find the SpO_2 saturation in an empirically derived equation into the Masimo SET® Intellivue software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia states during motion and non-motion conditions.

Method of Operation

The Masimo SET® Intellivue pulse oximeter Module is installed in an empty slot in a compatible Philips IntelliVue Patient Monitoring System. An oximetery sensor is attached to a patient's finger and one end of a patient cable is connected to the sensor and the other end connected to the Masimo SET® Intellivue pulse oximeter Module.

The monitor will begin continuously displaying the patient's pulse rate, and SpO_2 value. The practitioner can then use the information that is continuously displayed on the monitor to help assess the condition of the patient and as an aide in determining if any intervention is required by the practitioner.

Once the practitioner determines the patient no longer requires monitoring, the cable is disconnected from the sensor, the oximetry sensor is removed (and disposed of if it is a single use device), and the power to the monitor is turned off.

Power Source

The Masimo SET® Intellivue pulse oximeter module is powered by the Philips IntelliVue Patient Monitoring System.

Specifications and Operating Ranges

Range		
	Saturation (% SpO_2)	1% - 100%
	Pulse Rate (bpm)	25 – 240
	Perfusion	0.02% - 20%
Accuracy		
	Saturation (% SpO_2) - During No Motion Conditions[1]	
	Adults, Pediatrics	70% - 100% ± 2 digits
		0% - 69% unspecified
	Neonates	70% - 100% ± 3 digits
		0% - 69% unspecified
	Saturation (% SpO_2) - During Motion Conditions[2,3]	
	Adults, Pediatrics[2]	70% - 100% ± 3 digits
		0% - 69% unspecified
	Neonates[3]	70% - 100% ± 3 digits

510(k) SUMMARY

	0% - 69% unspecified
Pulse Rate (bpm) - During No Motion Conditions[1]	
Adults, Pediatric, Neonates	25 to 240 ± 3 digits
Pulse Rate (bpm) - During Motion Conditions[2,3]	
Adults, Pediatric, Neonates	25 to 240 ± 5 digits

Resolution

Saturation (% SpO_2)	1%
Pulse Rate (bpm)	1

Low Perfusion Performance[4]

> 0.02% Pulse Amplitude	Saturation (% SpO_2) ± 2 digits
and % Transmission > 5%	Pulse Rate ± 3 digits

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.

Isolation

Patient Leakage current	Less than 100 μAmp
Dielectric Withstand (mains to patient)	>4000 VAC

Environmental

Operating Temperature	32°F to + 131°F (0°C to +55°C)
Storage Temperature	-40°F to + 158°F (-40°C to +70°C)
Relative Humidity	5% to 95% noncondensing
Operating Altitude	up to 15,000 ft

Circuitry

Microprocessor controlled
Automatic self-test of oximeter when powered on
Automatic setting of parameters
Automatic alarm messages

Audio indicators

Controlled by Philips IntelliVue Patient Monitoring System

Physical characteristics

Dimensions:	1.4" x 3.9" x 3.8" (36 mm x 99.6 mm x 97.5 mm)
Weight:	7.4oz. (209 g)

Modes

Averaging mode:	5, 10, 20 seconds
Sensitivity	Normal

1 The Masimo SET Technology with LNOP Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

2 The Masimo SET Technology with LNOP Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

3 The specified saturation accuracy from 70% - 100% for neonates is based on the results from clinical studies on adult volunteers and 1% was added to account for the properties of fetal hemoglobin to be within ± 3 digits during both motion and no motion conditions when compared to the CO-Oximeter, and the pulse rate accuracy values for neonates to be within ± 3 digits during no motion and ± 5 digits during motion conditions when compared to the ECG.. This variation equals plus or minus one standard deviation which encompasses 68% of the population

4 The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

Environmental Testing

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

Nonclinical tests performed that support a determination of substantial equivalence.

The Masimo SET® Intellivue Pulse Oximeters Module was subjected to bench testing using a simulator that determined the performance accuracy of the instruments against the simulator under the range of saturation and pulse rates that both devices specify.

The results of the bench testing showed that the Masimo SET® Intellivue Pulse Oximeter Module returned the same saturation accuracy values within ± 2 digits and pulse rate values within ± 3 digits when compared to the simulators used.

Clinical tests performed that support a determination of substantial equivalence.

Clinical studies were performed using the Masimo SET® technology on healthy adult volunteer subjects during no motion and 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 CO-Oximeter.

Clinical studies were performed using the Masimo SET® technology on healthy adult volunteer subjects who were subjected to low perfusion conditions and 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 CO-Oximeter.

Clinical studies were conducted following regulations under Title 21 of the Code of Federal Regulations (21CFR), Part 812 - Investigational Device Exemptions, Part 50 - Protection of Human Subjects and Part 56 - Institutional Review Boards.

The results from the clinical studies show that the Masimo SET® technology saturation accuracy values for adults and pediatrics within ± 2 digits during no motion conditions and ± 3 digits during motion conditions when compared to the CO-Oximeter and the pulse rate accuracy values within ± 3 digits during no motion conditions and ± 5 digits during motion conditions when compared to the ECG.

The specified saturation accuracy from 70% - 100% for neonates is based on the results from clinical studies on adult volunteers and 1% was added to account for the properties of fetal hemoglobin to be within ± 3 digits during both motion and no motion conditions when compared to the CO-Oximeter, and the pulse rate accuracy values for neonates to be within ± 3 digits during no motion and ± 5 digits during motion conditions when compared to the ECG.

510(k) SUMMARY

Conclusions

The results of the **environmetal testing** demonstrated that the Masimo SET® Intellivue Pulse Oximeter Module **met** the requirements of Reviewers Guidance for Premarket Submissions - November 1993.

The results of the **bench testing** demonstrates that the Masimo SET® Intellivue Pulse Oximeters Module **met** its performance requirements.

The results of the **clinical testing** demonstrates that the Masimo SET® Intellivue Pulse Oximeters Module **meets** its performance requirements during no motion and motion conditions and low perfusion conditions.

The **non-clinical and clinical testing** performed demonstrates that the Masimo SET® Intellivue Pulse Oximeters Module is safe, effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2004

Mr. James Cronin
Vice President, Regulatory Affairs/Quality Assurance
Masimo Corporation
2852 Kelvin Ave.
Irvine, CA 92614-5826

Re: K040259
Trade/Device Name: Masimo SET Intellivue Pulse Oximeter Module
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, DPZ
Dated: February 2, 2004
Received: February 4, 2004

Dear Mr. Cronin:

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.

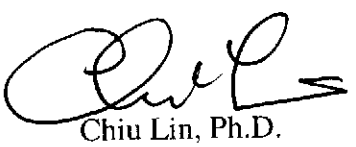
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Section 3 - Indications for Use

510(k) Number (if known):

Device Name: Masimo SET Intellivue Pulse Oximeter Module

Indications For Use:

The Masimo SET® Intellivue Pulse Oximeter Module 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 SET® Intellivue 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 and hospital-type facilities.

Prescription Use __X_____ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

0020

(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 Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K040259