

Traditional 510(k): NEW DEVICE PREMARKET NOTIFICATION  
for the OSI Medical, Inc. Dolphin Stand-Alone Pulse Oximeter

Summary of Safety and Effectiveness

June 30, 2000

Subject: Summary of Safety and Effectiveness Information for the OSI Medical Dolphin Stand-Alone Pulse Oximeter and Accessories.  
Proprietary: OSI Medical Dolphin Stand-Alone Pulse Oximeter, Model No. 2100 and Accessories.  
Common: Oximeter.  
Classification: Oximeter Class II – 21 CFR 870.2700 – 74 DQA

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

The OSI Medical Dolphin Pulse Oximeter and Accessories is substantially equivalent to the following currently marketed device(s):

- Masimo SET®/Quartz 2500 Pulse Oximeter and Accessories.

The OSI Medical Dolphin Pulse Oximeter and Accessories is a portable stand-alone device, connecting cable, and oximetry sensor(s) 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 LEDs within the sensor to determine the fractional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate, and provide for the connection to the connecting cable.

The OSI Medical Dolphin Pulse Oximeter is available in one configuration as a portable stand-alone oximeter that is 10 cm / 3.94 inches high, 27.5 cm / 10.83 inches wide, 25 cm / 9.84 inches deep and weighs about 4 kg / 8.8 lbs. 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 approximately 4 hours based upon 2 Ampere hour battery (200mA OEM Module, 300mA System Module) and a charge time of about 4.5 hours to 80% capacity.

The extension cable connects between the monitor and oximetry sensor(s) and transfers LED drive power and the calibration drive to the oximetry sensor from the monitor and the monitor receives the detector signal from the oximetry sensor.

The extension cable is available in one configuration and is approximately 8 feet / 2.44m in length, and the sensor(s) are approximately 18 inches / 45.72 cm in length.

The sensor(s) measure 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 oximetry sensor is available in only one configuration at this time, and with one configuration for the extension cable.

- A reusable clip-on finger oximetry sensor intended for adults and pediatrics greater than 30kg / 66.14 lbs.
- An extension cable for the sensor.
- Other sensors are currently under development

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(Summary of Safety and Effectiveness continued):

The OSI Medical Dolphin Stand-Alone Pulse Oximeter, Model No. 2100 and Accessories have been designed to comply with the following standards:

1. CSA C22.2 No. 601.1
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. ISO 9919: 1992
6. EN 865: 1997
7. FDA Guidance Document for Pulse Oximeters: 9/7/1992
8. ASTM 1415:1992, and Draft 10.1
9. UL2601-1: Second Edition, 1997
10. IEC 6068-2-6
11. IEC 6068-2-27
12. IEC 6068-2-64
13. ISTA Procedure 2A

The Masimo Set®/Quartz 2500 Pulse Oximeter and the OSI Medical Dolphin Stand-Alone Pulse Oximeter are substantially equivalent in design concepts, technologies and materials. The OSI Medical Dolphin Pulse Oximeter was validated through testing that, in part, support the compliance of the OSI Medical Dolphin Pulse Oximeter to the above mentioned standards. Additionally, the software for the OSI Medical Dolphin Pulse Oximeter was fully specified and validated by OSI Medical.

The OSI Medical Dolphin Stand-Alone Pulse Oximeter and Accessories achieve great advancements in digital signal processing, which represent a new generation of Pulse Oximetry products.

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