K962127

OHMEDA

▰▰▰ THE BOC GROUP

May 30, 1996

Subject:	510(k) Summary of Safety and Effectiveness Information for the Ohmeda 3800 Pulse Oximeter.
Proprietary:	Ohmeda 3800 Pulse Oximeter
Common:	Oximeter
Classification:	Oximeter Class II - 21CFR870.2700 - 74DQA

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

The Ohmeda 3800 Pulse Oximeter is substantially equivalent to the currently marketed Ohmeda 3760 Pulse Oximeter and the Ohmeda Handheld Pulse Oximeter.

The Ohmeda Model 3800 Pulse Oximeter is a noninvasive, arterial oxygen saturation and pulse rate monitor. It features two easy-to-read displays that present patient data and status information: a numeric LED (light-emitting diode) display that shows the SpO_2 and pulse rate values, and a plethysmographic LCD (liquid crystal display) that shows the waveform, the current high and low SpO_2 and pulse rate limit settings, and messages as appropriate. Features

- Several types of Ohmeda sensors for flexibility.
- An automatic self-test at start-up.
- Automatic tiered alarm messages.
- Backlit and adjustable viewing-angle display for excellent visibility in subdued lighting conditions.
- Direct access to user-selectable high and low alarm limits for SpO_2 and pulse rate.
- An audible pulse indicator with an adjustable volume; the automatic pitch modulation reflects changing SpO_2 level.
- Visual and audible (adjustable volume) alarms.
- An alarm-silence feature; silences audible alarms continuously until deactivated.
- Status and alarm informational messages appear on the LCD.
- Short, medium, or long SpO_2 response averaging modes.
- Adult or neonatal patient modes for default pulse rate alarm settings.
- Fractional or functional SpO_2 calibration modes.
- Automatic storage of up to 12 hours of SpO_2, pulse-rate, and alarm limit violations data in trend memory, which can be output through the RS-232 serial connector.
- Rechargeable, sealed, lead-acid battery backup operation, including low battery status reporting.
- Automatic scale plethysmographic waveform to provide a relative indication of the sensor site perfusion level.
- Larger SpO_2 digital display for clear differentiation from the pulse rate value.

The software for the Ohmeda 3800 Pulse Oximeter has been developed following a rigorous software development process and has been fully specified and validated by Ohmeda.

The Ohmeda 3800 Pulse Oximeter complies with the following standards:
1. CSA C22.2 #601
2. IEC 601-1, Part 1 and Amendment 1
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. UL 2601-1

The Ohmeda 3760 Pulse Oximeter, the Ohmeda Handheld Pulse Oximeter and the Ohmeda 3800 Pulse Oximeter are substantially equivalent in technological characteristics, theory of operation and measurement methods. The Ohmeda 3800 Pulse Oximeter is the next generation of oximeter, utilizing the technological advances of today to bring Ohmeda oximeters to the next century.