

K961644



Mine Safety Appliances Company • Instrument Division • P.O. Box 427 • Pittsburgh, PA 15230

Telephone: (412) 776-8600

WRITERS DIRECT DIAL NO.

**JUL 25 1996**

**510(K) SUMMARY**

**SUBMITTER:** Mine Safety Appliances Company  
P.O. Box 427  
Pittsburgh, Pennsylvania 15230

Telephone: 412-776-8600  
FAX: 412-776-8892

**CONTACT:** Thomas P. McClory  
Marketing Manager, Medical Products

**SUMMARY DATE:** April 17, 1996

**LOCATION:** Walden Road-Cranberry Twp. • Mars, PA 16046

NAME OF DEVICE: MiniOX® 3000 Oxygen Monitor  
COMMON NAME: Oxygen monitor  
CLASSIFICATION NAME: Oxygen gas analyzer (868.1720)  
MARKETED DEVICE: MiniOX® III Oxygen Monitor  
Mine Safety Appliances Company  
(K833326)

#### DEVICE DESCRIPTION

Battery operated and microprocessor controlled, the MiniOX® 3000 Oxygen Monitor measures oxygen concentrations in the 0 - 100% range. The performance features include a calibration function; high and low oxygen concentration alarms; low and depleted battery alarms; oxygen sensor indicator; automatic error detection; battery test and oxygen concentration alarm test.

The calibration function allows calibration of the device against room air (21% O<sub>2</sub>) or 100% O<sub>2</sub>. Audible and visual alarms alert the operator when monitor calibration is required. High and low oxygen concentration alarms may be set in the ranges of 19%-100% (high alarm) and 18%-99% (low alarm) or the default high/low settings may be used (50% and 18% respectively). Audible and visual alarms activate when oxygen concentrations fall below the preset (or default) low alarm setting or rise above the preset (or default) high alarm setting. The MiniOX® 3000 Oxygen Monitor detects low and depleted battery conditions and activates audible and visual alarms. The MiniOX® 3000 Oxygen Monitor also alarms for sensor disconnection or malfunction and for various internal operating errors.

The MiniOX® 3000 Oxygen Monitor conducts self checks at power-up (battery installation), turn-on, and during operation. Additionally, the monitor has two operator initiated test functions. The Alarm Test verifies the operation of the high and low oxygen level alarms; the Battery Test assesses the relative remaining battery life.

The MiniOX® 3000 Oxygen Monitor consists of two components: the instrument and the oxygen sensor. The portable, hand-held instrument features a touch sensitive keypad; a liquid crystal display (LCD) that shows monitor status, continuous oxygen concentrations, and preset alarm levels; and two red light emitting diodes (LED) which serve as visual alarms. The back of the instrument case has a bail bar which allows the instrument to "stand" on a horizontal surface during monitoring operations. A plastic wedge on the back of the instrument slides into an optional bracket for mounting the instrument on a horizontal or vertical pole.

The oxygen sensor used in the MiniOX® 3000 Oxygen Monitor is the same oxygen sensor used in Mine Safety Appliances Company oxygen monitoring medical devices for the past 15 years. Connected to the instrument by a coiled cable, the galvanic oxygen sensor consists of a deflector assembly and a plastic housing containing two electrodes. A coiled cable connects the sensor to the instrument. Plugs at each end of the cable snap into jacks (one located in the sensor housing and one located in the instrument) and are held securely in place by twist collars.

In addition to the mounting bracket, the device has two accessories: a tee adapter and a retaining strap. The oxygen sensor is introduced into a breathing circuit through a Mine Safety Appliances Tee Adapter which connects two lengths of tubing. The

sensor/tee assembly is positioned with the sensor deflector pointing downward to ensure that moisture does not collect on the sensor membrane. A Retaining Strap ensures that the sensor remains securely in place in the Tee Adapter.

#### INTENDED USE

The MiniOX® 3000 Oxygen Monitor provides continuous, direct monitoring of oxygen mixtures in a wide variety of medical applications such as anesthesiology (e.g., anesthesia machines), respiratory therapy (e.g., respirators, ventilators, pediatric incubators), and oxygen therapy (e.g., oxygen tents). The MiniOX® 3000 Oxygen Monitor is to be used by trained health care professionals under the supervision, or on the order, of a physician in a hospital (or other clinical setting) and during emergency transport.

#### COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The technology used in the MiniOX® 3000 Oxygen Monitor and the MiniOX® III Oxygen Monitor is the same with the exception of the technology used in the design of the printed circuit boards.

#### SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Except instrument weight, the specifications of the MiniOX® 3000 Oxygen Monitor and the MiniOX® III Oxygen Monitor are identical. It was determined that it was necessary to conduct performance tests to verify that the MiniOX® 3000 Oxygen Monitor meets its specifications and, thereby, demonstrate that the monitor is substantially equivalent to the MiniOX® III Oxygen Monitor. Table 1 summarizes the tests that were conducted.

#### Conclusions Drawn From Testing

The MiniOX® 3000 Oxygen Monitor and the MiniOX® III Oxygen Monitor have the same specifications. Therefore, in order to demonstrate substantial equivalence, it is necessary to verify that the MiniOX® 3000 Oxygen Monitor does, indeed, perform to specification. Because many of the specifications were derived from applicable voluntary standards and FDA guidances, the MiniOX® 3000 Oxygen Monitor was tested according to test protocols based on these standards and guidances.

Tests results verified that the device conforms to the applicable sections of ANSI Z79.10, the Reviewer Guidance for Premarket Notification Submissions, and the Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review. Test results also demonstrated that the MiniOX® 3000 Oxygen Monitor performs to specification and, therefore, is substantially equivalent to the legally marketed device, the MiniOX® III Oxygen Monitor.

Non-Clinical Performance Test Summary		
Test	Standard/Guidance	Results
Response Time	ANSI Z79.10 <sup>1</sup> 4.3.2.1	Pass
Reading Accuracy	ANSI Z79.10 3.2.1.1	Pass
Ambient Operating Temperature	ANSI Z79.10 3.2.3.1 FDA MDS 201-0004 <sup>2</sup>	Pass
Storage Temperature	ANSI Z79.10 3.2.3.2 FDA MDS 201-0004	Pass
Humidity/Condensation Effects	ANSI Z79.10 3.2.1.4	Pass
Stability	ANSI Z79.10 3.2.1.2	Pass
Electromagnetic Compatibility	ANSI Z79.10 3.2.3.4 FDA MDS 201-0004	Pass
Shock and Vibration	ANSI Z79.10 3.2.3.3 FDA MDS 201-0004	Pass
Battery Operation Time	FDA MDS 201-0004	Pass
Audible Alarm Output	ANSI Z79.10 3.2.2.3.1 FDA MDS 201-0004	Pass
Battery Reversal (reverse polarity)	FDA MDS 201-0004	Pass
Shipping/Handling Shock Resistance	MIL-STD 516-4	Pass
Fluid Spill	IEC 601-1, 529 FDA MDS 201-0004	Pass
Function (Performance Features)	FDA Guidance <sup>3</sup>	Pass
Oxygen Alarm Accuracy	ANSI Z79.10 3.2.1.3 FDA MDS 201-0004	Pass

Table 1

- <sup>1</sup> Requirements for Oxygen Analyzers for Monitoring Patient Breathing Mixtures  
<sup>2</sup> Reviewer Guidance for Premarket Notification Submissions  
<sup>3</sup> Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review