JUL 21 1998

16 510(k) SUMMARY

K971084

SUBMITTER:	Oxigraf, Inc.
NAME OF DEVICE:	Model O2 Oxygen Analyzer Model O2 Fast Oxygen Analyzer
COMMON NAMES:	Oxygen Monitor, Oxygen Sensor
CLASSIFICATION NAME:	Oxygen gas analyzer (868.1720)
MARKETED PREDICATE DEVICE:	MiniOx 3000 Oxygen Monitor Mine Safety Appliances Company K961644, K833326
SUMMARY DATE:	March 9, 1998
CONTACT:	Bruce W. McCaul, President

The Model O2 Oxygen Analyzer measures and displays oxygen concentration in the range from 5 to 100% to provide patient monitoring of oxygen mixtures in anesthesiology, respiratory therapy, and oxygen therapy.

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INTENDED USE The Model O2 is intended to provide continuous, direct patient monitoring of oxygen mixtures in a wide variety of medical applications such as anesthesiology (e.g., anesthesia and breathing machines), respiratory therapy (e.g., breathing circuits, respirators, ventilators and pediatric incubators), and oxygen therapy (e.g., oxygen concentrators, tents, masks and nasal cannulas). The Model O2 is designed to be used by trained health care professionals under the supervision of a physician in a hospital, clinic, or emergency medicine setting.

DEVICE DESCRIPTION The Model 02 Fast Oxygen Analyzer consists of laser diode oxygen sensor, sampling pump, pressure sensor, flow and gas temperature controllers, displays, keypad, and alarm packaged in an instrument case. The oxygen concentration displayed is corrected with respect to any changes in barometric or ambient temperature. Calibration may be performed using the keypad and display prompts. Audible and visual alarms are available for low and high oxygen concentration and for low flow and high pressure. The unit is powered by an external 12 volt, 2 amp universal input power supply. Non-sterile inlet filters and airway adapter sets labeled "single patient use" remove water from the sampled gas.

The Oxygen Analyzer display is selected by pressing one of keys on the keypad: 02, Alarm, Flow, or Cal. The 02 display, showing the measured oxygen concentration in the upper display and the alarm settings in the lower display, is the primary and default display after warm-up; the O2 display is the only display where alarms are active. In order to prevent inadvertent disabling of alarms, the display will return to the 02 measurement within 20 seconds if no keystroke is made. If an alarm is detected, the warning tone will sound and the alarm condition will be flashed in the lower display; the alarm tone and flashing will continue until the Next (Silence) key is pressed. If the alarm condition is still present, it will be indicated in the lower display, but the tone and flashing will be inhibited for 20 seconds. When the alarm condition is corrected and the Next key is pressed, the O2 display returns.

The other displays are used to view and set various operating parameters. The Alarm display is used to set alarm thresholds. Alarms may be set for any value from Off to 99 for the low oxygen alarms and from Off to 100 for the high oxygen alarms. The lower display shows the low and high alarm settings in the form, for example, 18< >90. The alarm sound volume may be adjusted from 4 to 10 in Basic Operation.

The Flow display shows the sample flow rate while the lower display shows ml/min. The Plus(+) and Minus(-) keys change the flow rate from 50 ml/min for neonatal applications to 150 ml/min for adult applications.

The Cal display enables calibration of the instrument. Only two cal gas values are allowed in Basic Operation, 20.9 and 100%. Pressing the Cal key switches from one set point to the other. The lower display shows the set point while the upper display shows the deviation of the oxygen measurement from the set point if the

deviation is less than x%. If the deviation is large, a row of arrows prompts that the wrong cal gas is present. When the operator has introduced the appropriate cal gas at an acceptable pressure, the deviation will be displayed. Pressing the Set key records new cal scale factors reducing the deviation to zero. The analyzer will accept updates of either the high or low set points. Calibration is recommended whenever a humidity change occurs or at least once every 400 hours.

The Oxigraf analyzer uses absorption spectroscopy in the visible spectrum near 760 nm, similar to the absorption spectroscopy method used to measure CO_2 and anesthetic gases in the infrared spectrum. However, the oxygen absorption is in a region of the visible spectrum where there is no interference or absorption by other gases. And the light source used for oxygen is a laser diode compared to the incandescent source used in infrared spectroscopy.

The emission linewidth of the laser diode source used by Oxigraf for oxygen measurement and the absorption linewidth of the individual electronic-rotational lines of O_2 are very narrow, both less than 0.01 nm, compared to perhaps 100 nm for the CO_2 absorption band at atmospheric pressure. The specificity of the laser diode spectroscopy is thus much greater than the black-body radiation and filter technique of infrared spectroscopy. The spectrally pure laser is tuned thermally and electronically to the oxygen absorption line. As the oxygen concentration increases, the light intensity is attenuated. The photodetector response varies linearly with oxygen concentration because absorption by the oxygen is weak.

COMPARISON TO MARKETED DEVICE The legally marketed predicate device is the electrochemical oxygen sensor such as the MSA MiniOx III/3000.

- The Oxigraf Model O2 measures with a response time of 0.1 seconds; while the predicate device responds in about 10 seconds.
- The Model O2 measures the oxygen partial pressure and the gas sample pressure to display the true oxygen concentration; the predicate device has no pressure sensor and therefore must be recalibrated whenever the sampling pressure or atmospheric pressure changes.
- The Model O2 corrects for changes in gas sample temperature and therefore needs calibration less frequently than the predicate device.
- The Model O2 is insensitive to the type of foreign gas mixture compared to other monitors.
- The Model O2 includes a sampling pump, flow controller, and low flow alarm to provide diverting or sidestream sampling of respiratory gases.

The calibration and high and low oxygen concentration alarm features of the Oxigraf analyzer are similar to the predicate device. Neither analyzer is corrected for the dilution effect of humidity; both analyzers are calibrated as if the cal gas were dry, and therefore need calibration when the humidity changes.

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Manufacturer	Oxigraf Model 02 Oxygen Analyzer	MSA MiniOx III/3000 Oxygen Monitor
Range	5 -100%	0 -100% oxygen
Resolution	0.1%	0.1%
Humidity Range	0 - 95% RH	5 - 95% RH
Alarm	Yes, hi/low audible/visible	Yes, hi/low audible/visible
Response Time	10 to 90% in 133 ms @ 150 ml/min.	90% in 8 sec @ 2000 ml/min.
Accuracy	± 0.2%	± 1% @ constant pressure/temp
Linearity	± 0.2%	± 1% @ constant pressure/temp
Accu. + Lin.	± 0.5%	± 2% @ constant pressure/temp
Cross-Sensitivity	0.2% all anesthetic gases	0.5%, Desflurane 0.9% Halothane 2.3% Methoxyflurane 0.8% Nitrous Oxide
Pressure	± 0.2%, 75 to 120 kPascal	Not corrected; % varies w. pressure
Temperature	± 0.2%, 0 to 35 C	3%, 0 to 40 C
Time to service	10,000 hours	1200 hours battery, 7500 hours sensor
Dimensions	3 x 7.5 x 11" H x W x D	6 x 3.3 x 1.3"
Weight	5 pounds	1 pound
Sensor Technology	Laser diode absorption spectroscopy	Galvanic gold/lead in KOH electrolyte
Intended use	Same	Same

SUMMARY OF PERFORMANCE TESTING Extensive bench testing has been carried out comparing especially the linearity of response and the cross-sensitivity to other gases. The laser diode technology compares favorably with the electrochemical technology.

The results of actual laboratory bench testing using certified calibration gas mixtures for linearity, cross-sensitivity to common anesthetic and atmospheric gases, and sensitivity to environmental changes in temperature, humidity, and ambient atmosphere are summarized in the table below.

Manufacturer	Oxigraf Model 02 Oxygen Analyzer	MSA MiniOx III/3000 Oxygen Monitor
Response Time 21% to 100%	0.25 to 99.75% in 1.1 s @ 150 ml/min.	0.25 to 99.75% in 147 s @ 2000 ml/min.
Response Time 21% to 100%	10 to 90% in 133 ms @ 150 ml/min.	10 to 90% in 8 sec @ 2000 ml/min.
Accuracy	± 0.0%	± 0% @ constant pressure/temp
Linearity	± 0.2%	± 0.3% @ const. pressure/temp

Accu. + Lin.	± 0.2%	± 0.3% @ const. pressure/temp
Cross-Sensitivity	+0.1%, -0.3%, all anesthetic gases	0.4%, Desflurane 1.0% Halothane 0.9% Isoflurane 0.8% Nitrous Oxide
Pressure	± 0.2%, 80 to 110 kPascal	Not corrected; % varies w. pressure
Temperature	± 0.2%, 0 to 35 C	3%, 0 to 40 C
Humidity	Not corrected	Not corrected

In addition, the Model O2 has been tested to comply with various environmental standards required in the "Reviewer Guidance for Premarket Notification Submissions" of the Anesthesiology and Respiratory Devices Branch of the FDA and to the software verification and validation requirements of "Reviewer Guidance for Computer Controlled Medical Devices" of the Office of Device Evaluation, CDR/FDA.

SUBSTANTIAL EQUIVALENCE Substantial equivalence is based on the fact that the Model O2 has the same intended used and similar technological characteristics as the predicate device. In instances where the technological characteristics are different, it has been demonstrated by bench testing that there are no new questions raised regarding safety or efficacy. Therefore, it can be concluded that the Model O2 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 1998

Mr. Charles F. Brothers
Oxigraf, Inc.
1170 Terra Bella Avenue
Mountain View, CA 94043

Re: K971084
Model 02 Oxygen Analyzer
Regulatory Class: II (two)
Product Code: 73 CCL
Dated: June 30, 1998
Received: July 2, 1998

Dear Mr. Brothers:

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.

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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INTENDED USE

The Model O2 is intended to provide continuous, direct patient monitoring of oxygen mixtures in a wide variety of medical applications such as anesthesiology (e.g., anesthesia and breathing machines), respiratory therapy (e.g., breathing circuits, respirators, ventilators and pediatric incubators), and oxygen therapy (e.g., oxygen concentrators, tents, masks and nasal cannulas). The Model O2 is designed to be used by trained health care professionals under the supervision of a physician in a hospital, clinic, or emergency medicine setting.

This intended use is the same as the use statement for the predicate device, copied here:

> "The MiniOX 3000 Oxygen Monitor provides continuous, direct monitoring of 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."

Information about the predicate legally-marketed device to which substantial equivalence is claimed is appended after Section 5, the Discussion of Similarities and Differences.

Proposed labeling and the Instruction Manual for the Oxigraf Model O2 are in Section 14.

prescriptions use ✓

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

510(k) Number _____