K973282

510 (k) SMDA SUMMARY

1.0 Date:
August 28, 1997

MAR - 4 1998

2.0 Submitter:
Ceramatec, Inc.
2425 South 900 West
Salt Lake City, Utah 84119

3.0 Contact Person:
Gordon Roth
Quality System Manager

4.0 Telephone:

Phone Direct:	(801) 978-2117
Phone Business:	(801) 972-2455
FAX	(801) 972-1925

5.0 Proprietary Device Name:
Ceramatec® Handi

6.0 Classification Name:
Oxygen Gas Analyzer

7.0 Common Name:
Oxygen Analyzer

8.0 Predicate Device:
MSA Miniox® IA oxygen analyzer (K935370)

9.0 Device Function:
The device function of the Ceramatec® Handi oxygen analyzer is to monitor oxygen concentration in the patient environment.

10.0 Method of Operation:

The Ceramatec® Handi oxygen analyzer is comprised of a galvanic oxygen sensor and an analyzer module. The galvanic oxygen sensor produces a millivolt output that is proportional to the partial pressure of oxygen in the monitored gas. The analyzer module contains an electronic circuit that converts the millivolt output of the sensor to a digital percent-oxygen reading on a liquid-crystal display (LCD).

The electronic circuit includes an "ON" button, a calibration potentiometer, and a two-digit LCD. The "ON" button is used to power-on the instrument. The LCD is blank when the Handi is in power-off mode. When the "ON" button is pressed, the unit begins to display the percent-oxygen concentration of the monitored gas. The unit is equipped with an auto-off circuit that automatically turns the device off approximately 1.3 minutes after power-on. The device also contains a low-battery detection circuit to safeguard against faulty readings due to a low-battery condition. When a low-battery condition is detected, the low-battery detection circuit prevents operation of the device by immediately powering-down the analyzer upon release of the "ON" button.

The calibration potentiometer allows the device to be calibrated against a gas of a known oxygen concentration, such as air (21% oxygen) or 99% oxygen. The two-digit LCD provides direct readout of percent-oxygen concentration. An over-range indication is included on the LCD to differentiate between 0% oxygen and 100% oxygen.

Please find the attached functional flow-diagram illustrating the operation of the Ceramatec® Handi oxygen analyzer.

The galvanic oxygen sensor is a lead-oxygen battery consisting of a lead anode, and an oxygen cathode. The oxygen cathode is made up of gold and an aqueous electrolyte solution. The gold electrode is in close proximity to a non-porous fluoropolymer membrane. Oxygen permeating through the membrane is reduced electrochemically at the gold electrode. An electronic network, consisting of resistors and / or thermistors for temperature compensation, is connected between the cathode and anode. This allows the lead-oxygen battery to continually discharge in the presence of oxygen. The voltage across the resistor / thermistor network is proportional to the oxygen partial pressure of the gas in contact with the fluoropolymer membrane. This voltage is converted by the analyzer to a digital output that is displayed on the LCD.

11.0 Materials of Construction:

Corrosion-Resistant Plastic:	Housing
LCD:	Display
Potentiometer:	Calibration
Epoxy-Resin Circuit Board:	Printed Circuit Board
Lithium Battery:	Power Source
Galvanic Fuel-Cell Oxygen Sensor	Sensor

12.0 Product Specifications:

PRODUCT	*CERAMATEC® HANDI*
Display Range	0-99% oxygen
Display Resolution	1% oxygen
Warm-up time	none required
Operating Temperature Range	10 - 40°C
Operating Humidity Range	0-95% RH non-condensing
Accuracy	±3% full-scale
Linearity	±2% full-scale
Sensor type	galvanic fuel sensor 0-100% O_2
Sensor Operating Life	12 months under normal operating conditions
Sensor Shelf Life	6 months
Storage Temperature	-15° - 50 °C
90% FS Response Time	<15 Seconds @ 25 °C
Interference	±2% full-scale
Low-Battery Indicator	instantaneous shut-off
Power Requirement	lithium button-cell battery
Battery Life	1100 hours
Instrument Weight	approximately 3 ounces

13.0 Intended Use:

The intended use of the Ceramatec® Handi oxygen analyzer is to monitor the oxygen concentration in the patient-breathing environment.

14.0 Patient Population:

The patient population of the Ceramatec® Handi oxygen analyzer consists of those patients who require the oxygen concentration in their environment to be monitored.

15.0 Comparison of Technological Characteristics:

PRODUCT	*MSA MINIOX® IA*	*CERAMATEC® HANDI*
Display Range	0-100% oxygen	0-99% oxygen
Display Resolution	0.1% oxygen	1% oxygen
Warm-up time	none required	same
Operating Temperature Range	0 - 40°C	10 -40 °C[5]
Operating Humidity Range	0-95% RH non-condensing	same
Accuracy	±3% full-scale[6]	same
Linearity	±2% full-scale	same
Sensor type	galvanic fuel sensor 0-100% O_2	same
Sensor Operating Life	12 months under normal operating conditions	same
Sensor Shelf Life	6 months	same
Storage Temperature	-20 - 55 °C	-15° - 50 °C
90% FS Response Time	<15 Seconds @ 25 °C	same
Interference	±2.3% full-scale	±2% full-scale
Low-Battery Indicator	LO BAT appears on LCD	instantaneous shut-off
Power Requirement	9 V alkaline battery	lithium button-cell battery
Battery Life	1400 hours	1100 hours
Instrument Weight	11 ounces	approximately 3 ounces

16.0 Conclusion:

In conclusion, based on the information provided, it has been determined that the Ceramatec® Handi oxygen analyzer is substantially equivalent to MSA Miniox® IA oxygen analyzer is safe and effective for its intended use.

[5] Since the patient breathing-environment is a controlled environment, oxygen analyzers are not typically exposed to temperatures between 0 - 10 °C. ANSI Z79.10 Section 3.2.3.1 specifies that an oxygen analyzer used in a patient breathing environment shall be capable of operating in a temperature range of 15-40 °C. The operating temperature range of the Handi is well within the ANSI specification. Therefore the operating temperature and relative humidity specifications of the Ceramatec® Handi oxygen analyzer and the predicate device are equivalent.

[6] Calculated per temperature effects in MSA Operating Manual, page 5-3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 1998

Mr. Gordon Roth
Quality Systems Manager
Ceramatec Inc.
2425 South 900 West
Salt Lake City, UT 84119

Re: K973282
Handi Oxygen Analyzer
Regulatory Class: II (two)
Product Code: 73 CCL
Dated: December 5, 1997
Received: December 8, 1997

Dear Mr. Roth:

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 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/dsmamain.html".

Sincerely yours,

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

Enclosure

510K Number (if known) : _____

Device Name: Ceramatec Handi Oxygen Analyzer

Indication for Use:

Purpose: The purpose of the Ceramatec® Handi oxygen analyzer is to monitor oxygen concentration in the patient breathing environment.

Function: The Ceramatec® Handi oxygen analyzer measures the oxygen partial pressure of a gas stream, and displays a digital reading of the oxygen concentration of the measured gas on a liquid-crystal display (LCD).

Target Patient Population: The target patient population consists of patients who require the oxygen concentration in their environment to be monitored.

Environment of Use: The Ceramatec® Handi oxygen analyzer is used in patient breathing environments whose temperatures range from 10 to 40 °C, and whose relative humidity ranged from 0 - 95% (non-condensing).

Device Claims: The Ceramatec® Handi oxygen analyzer has the claim of monitoring percent-oxygen concentration in the patient breathing environment.

Legally Marketed Predicate Device: The legally marketed predicate device is the MSA Miniox® IA oxygen analyzer. The predicate device was assigned 510(k) number K935370 and declared substantially equivalent by FDA.

Safety and Effectiveness: No differences in intended use or application of the Ceramatec® Handi or MSA Miniox® IA have been identified that could affect product safety or effectiveness.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Ring

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
5 10(k) Number K973282

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)