K972992

SECTION 21

510 (k) SMDA SUMMARY

1.0 Date:
August 5, 1997

MAR 30 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:
MAXCELL-1 Oxygen Sensor
MAXCELL-11 Oxygen Sensor
CAG-2 Oxygen Sensor
CAG-8 Oxygen Sensor
CAG-9 Oxygen Sensor
CAG-10 Oxygen Sensor
CAG-12 Oxygen Sensor
CAG-13 Oxygen Sensor
CAG-15 Oxygen Sensor
CAG-17 Oxygen Sensor
CAG-18 Oxygen Sensor
CAG-19 Oxygen Sensor
CAG-250 Oxygen Sensor

6.0 Classification Name:
Oxygen Gas Analyzer

7.0 Common Name:
Galvanic Oxygen Sensor

8.0 Predicate Device:

Seatronics Company, Inc. family of galvanic oxygen sensors.

9.0 Device Function:

Monitor oxygen concentration in the patient environment.

10.0 Method of Operation:

Ceramatec galvanic oxygen sensors are lead-oxygen batteries consisting of a lead anode and an oxygen cathode. The oxygen cathode is to be 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 one or more resistors and/or thermistors for temperature compensation, is connected between the cathode and anode which allows the lead-oxygen battery to continually discharge in the presence of oxygen. The said network may reside either within the sensor or be incorporated in an attached analyzer.

The current that flows through the device is proportional to the partial pressure of oxygen of the gas in contact with the fluoropolymer membrane. An attached analyzer detects the oxygen concentration by measuring the voltage between the ends of the resistor network.

The following electrochemical reaction occurs in Ceramatec galvanic oxygen sensors:

Cathode: $O_2 + 4\,e^- \rightarrow 2O^{2-}$

Anode: $2Pb \rightarrow 2Pb^{2+} + 4e^-$

Although a sensor is sealed against electrolyte leakage, it is open to ambient atmosphere so it can detect oxygen. The membrane is chosen to govern gas flow into the sensor to give a good compromise between sensor response and environmental tolerance. A more open membrane may give faster response, but allows ingress of other atmospheric species such as acid vapor and water vapor.

In summary, Ceramatec galvanic oxygen sensors are designed to provide a current output that, at constant temperature and pressure, is linearly proportional to the oxygen partial pressure.

Both the Ceramatec family of galvanic oxygen sensors and the predicate device family operate in the manner described above.

SECTION 21

510 (k) SMDA SUMMARY

11.0 Device Materials of Construction:

Housing:	Corrosion-resistant plastic
Anode:	Lead
Cathode:	Gold
Membrane:	Fluoropolymer
Sealing:	Elastomeric polymer
Separator	Porous Polymeric Sheet

12.0 Device Specifications:

Product Specifications

PRODUCT	*MAXCELL-1*	*CAG-2*	*CAG-9*	*CAG-12*	*CAG-250*
RANGE	0-100%	SAME	SAME	SAME	SAME
ACCURACY	±2% @ constant T, P	SAME	SAME	SAME	SAME
90% RESPONSE TIME	<20 s.	SAME	SAME	SAME	SAME
TEMPERATURE RANGE	5 - 40 °C	SAME	SAME	SAME	SAME
HUMIDITY	5-95% non-condensing	SAME	SAME	SAME	SAME
INTERFERENCE	±2%	SAME	SAME	SAME	SAME
LINEARITY	±2%	SAME	SAME	SAME	SAME
OPERATING LIFE	>12 MONTHS	SAME	SAME	SAME	SAME
STORAGE TEMPERATURE	-15 - 50 °C	SAME	SAME	SAME	SAME

13.0 Intended Use:

Monitoring of oxygen concentration.

14.0 Patient Population:

Those patients who require the oxygen concentration in their breathing environment to be monitored.

SECTION 21

510 (k) SMDA SUMMARY

15.0 Comparison of Technological Characteristics:

Comparitive Results*

PRODUCT	*SEATRONICS*	*MAXCELL-1*	*CAG-2*	*CAG-9*	*CAG-12*	*CAG-250*
RANGE	0-100%	SAME	SAME	SAME	SAME	SAME
ACCURACY	±2% @ constant T, P	SAME	SAME	SAME	SAME	SAME
90% RESPONSE TIME	<20 s	SAME	SAME	SAME	SAME	SAME
TEMPERATURE RANGE	0 °C-40 °C	5 ° -40 °C†	SAME	SAME	SAME	SAME
HUMIDITY	5-95%	SAME	SAME	SAME	SAME	SAME
INTERFERENCE	±2%	SAME	SAME	SAME	SAME	SAME
LINEARITY	±2%	SAME	SAME	SAME	SAME	SAME
OPERATING LIFE	12 MONTH	>12 MONTHS	SAME	SAME	SAME	SAME

16.0 Conclusion:

In summary, based on the information provided, it has been determined that the Ceramatec, Inc., family of galvanic oxygen sensors is substantially equivalent to the Seatronics Company family of galvanic oxygen sensors and are safe and effective for their intended use.

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* MAXCELL 11 is the dual-cathode version of the MAXCELL-1. Otherwise, they are identical and will be treated as one.

CAG-2, CAG-8, and CAG-10 differ only in body shape and electronic connection and are otherwise identical. Therefore, the CAG-2, CAG-8 and the CAG-10 will be treated as one.

CAG-9, CAG-15, CAG-18, and CAG-19 differ only in body shape and electronic connection and are otherwise identical. Therefore they will be treated as one.

CAG 12, CAG 13, and CAG-17 differ only in electronic connection and will therefore be treated as one.

† Since the patient breathing environment is a temperature-controlled setting, the galvanic oxygen sensors are not typically used at 0 °C to 5 °C. Therefore, the operating temperature ranges of the Ceramatec family of galvanic oxygen sensors and the Seatronics family of galvanic oxygen sensors are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 30 1998

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

Re: K972992
Ceramatec Maxcell and Cag Galvanic Oxygen Sensors
Regulatory Class: II (two)
Product Code: 73 CCL
Dated: January 8, 1998
Received: January 9, 1998

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) : K972992

Device Name: Ceramatec MAXCELL and CAG Galvanic Oxygen Sensors

Indication for Use:

Purpose: The purpose of the Ceramatec family of galvanic oxygen sensors is to be the oxygen-sensing component in a finished medical device that monitors oxygen concentration.

Function: The Ceramatec galvanic oxygen sensors are used in finished medical device products such as oxygen monitors, oxygen analyzers, ventilators and humidifiers.

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

Environment of Use: The Ceramatec family of galvanic oxygen sensors is used in finished medical devices (i.e., oxygen monitors, oxygen analyzers, ventilators, humidifiers, etc.) in patient environments whose temperatures range from 5 °C – 40 °C and from 5% - 95% relative humidity (non-condensing).

Device Claims: The Ceramatec family of galvanic oxygen sensors consists of oxygen sensing components in finished medical devices that have the indication or claim of monitoring oxygen concentration in the patients' breathing environment.

Legally Marketed Predicate Device: The legally marketed predicate device is Seatronics Company's family of galvanic oxygen sensors. The predicate device was assigned 510(k) number K953351 and was declared substantially equivalent by FDA.

Safety and Effectiveness: No differences in intended use or application of the Ceramatec family of galvanic oxygen sensors or the predicate device family have been identified that could affect safety or effectiveness.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number OEM 7 Part 1

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

(Optional Format 1-2-96)