510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Regulatory Submissions Manager
Date submission was prepared: May 25, 1999

2. Trade Name, Common Name and Classification Name:

A. Trade Name:
Siemens FiO2 Sensor

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Analyzer, Gas, Oxygen, Gaseous-Phase	73CCL	II	868.1720

3. Predicate Device Identification:
Mine Safety Appliances Company
MiniOX® 3000 Oxygen Monitor
510(k) K961644

4. Device Description:
The FiO2 Sensor is an addition to the Siemens INFINITY patient monitoring series that measures the oxygen concentration of ambient air in non-pressurized environments such as that found in infant incubators and oxygen hoods. In conjunction with the INFINITY NeoMed pod, the FiO2 Sensor permits oxygen concentration monitoring to be displayed on the INFINITY modular bedside monitors, MultiView WorkStations, and PC's via the INFINITY network.

5. Intended Use:
The intended use of Siemens FiO2 Sensor is to monitor the oxygen level of ambient air in non-pressurized environments such as that found in infant incubators and oxygen hoods.

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Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
USA
Tel: (978) 907-7500
Fax: (978) 750-6879
Telex: 511958 (Siemensm SD)

6. Table of Device Similarities and differences to predicate device

	Substantial Equivalent Device	Applicant	Explanation of Differences
Manufacturer	Mine safety Appliances Company MiniOx® 3000 Oxygen Monitor	Siemens Medical Systems FiO2 Sensor	
510(k) Number	K961644	To be assigned	
Intended Use	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).	Siemens FiO2 sensor is used to monitor the oxygen level of ambient air in non-pressurized environments such as that found in infant incubators and oxygen hoods.	Siemens FiO2 is not intended for use in ventilator breathing circuits.
Intended Population	All patient populations	Infant	
Intended Environment	Hospital or other clinical setting and during emergency transport.	In an environment where healthcare is provided by healthcare professionals.	
O2 Alarm System	Low/High O2 Alarm	Same	
Calibration	21% O2 or 100%O2	Same	
Measuring range	0-100%	5-100%	Measuring range is appropriate for intended use and intended population.
Accuracy	±1% FS (at RTP)	$\leq$3% FS (at RTP)	Meets the requirements of ISO 7767
Nominal Response time	97% in 30 seconds (2L/min at RTP)	Same	
Sensor Type	Galvanic fuel sensor	Same	
OperatingTemperature range	0°C to 40°C (32°F to 104°F)	10°C to 40°C (50° to 104°F)	Operating temperature range is consistent with that of the monitor.

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7. Assessment of non-clinical performance data for equivalence: Exhibit T

8. Assessment of clinical performance data for equivalence: Not Applicable

9. Biocompatability:
Not applicable

10. Sterilization:
Not applicable

11. Standards and Guidances: Exhibit U

COMPANY CONFIDENTIAL

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 1999

Mr. Penelope Greco
Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923

Re: K991884
Siemens FiO2 Sensor
Regulatory Class: II (two)
Product Code: CCL
Dated: August 27, 1999
Received: August 30, 1999

Dear Mr. Greco:

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,

Ceila M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991884

Device Name: **Siemens FiO2 Sensor**

Indications for Use:

Siemens FiO2 sensor is indicated for use in an environment where patient care is provided by healthcare professionals, i.e. Physicians, Nurses, Technicians, when the professional determines that the device is required to monitor the oxygen level of ambient air in non-pressurized environments such as that found in infant incubators and oxygen hoods.

MRI Compatibility Statement:
The Siemens FiO2 sensor is not intended for use in a MRI magnetic field.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991884