K 965062

JUN - 4 1997

510(k) SUMMARY

as required per 807.92(c)

2: Submitters Name, Address:

Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923
Tel: (508) 750-7500
Fax: (508) 777-3398
Official Correspondent: David Simard, Director Quality Assurance and Regulatory Affairs
Contact person for this submission: Jacqueline E. M. Emery
Date submission was prepared: December 9, 1996

3: Trade Name, Common Name and Classification Name:

A. Trade Name: Siemens SC9000/ SC9015 Series MULTIGas [tm] Module
Siemens SC9000/SC9015 Series MULTIGas+ [tm] Module

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

Common Name	Classification Number	Class	Regulation Number
Cardiac monitor	74DRT	II	21 CFR 870.2300
Arrhythmia detector & Alarm System	74DSI	III	21 CFR 870.1025
Breathing frequency monitor	73BZQ	II	21 CFR 868.2375
Pulse rate monitor	74BWS	II	21 CFR 870.2300
Non-indwelling blood pressure monitor	74DXN	II	21 CFR 870.1130
Clinical electronic thermometer	80BWX	II	21 CFR 880.2910
Pulse Oximeter	74DQA	II	21 CFR 870.2700
Cardiac Output Monitor	74KFN	II	21 CFR 870.1435
end-tidal Carbon-Dioxide Monitor	73CCK	II	21 CFR 868.1400
Indwelling Blood Pressure Monitor	74CAA	II	21 CFR 870.1110
Indwelling blood pressure monitor	74CAA	II	21 CFR 870.1110
Heart Rate Monitor, Neonatal	74FLO	II	21 CFR 870.2300
Ventilatory Effort Monitor (Apnea Detector)	73FLS	II	21 CFR 868.2375
Monitor Blood Pressure, Neonatal, Invasive	74FLP	II	21 CFR 870.1110

Multi Gas Monitor			
Analyzer, Gas, Carbon Dioxide, Gaseous	73CCK	II	21CFR868.1400
Analyzer, Gas, Enflurane Gaseous	73CBQ	II	21CFR868.1500
Analyzer, Gas, Halothane, Gaseous	73CBS	II	21CFR868.1620
Analyzer, Gas, Nitrous Oxide, Gaseous	73CBR	II	21CFR868.1700
Analyzer, Gas, Oxygen, Gaseous	73CCL	II	21CFR868.1720

4: Predicate Device Identification:

The MULTIGas modules use the same hardware, provided by the same OEM manufacturer, as the Hewlett-Packard model M1026A Anesthesia Gas Module Gas Module, cleared under 510(K) number K951127.

The SC9000/9015 Bedside Monitor System (510 (K) number K946306) provides the display and user interface capabilities for the MULTIGas [tm] modules.

5. Device Description

There are two multi gas modules being submitted as part of this 510(K) Notification: the MULTIGas[tm] (MGM) and the MULTIGas+ [tm] (MGM+). Both modules are free standing units that perform sidestream measurements of respiratory gases (CO_2, N_2O, and O_2) and anesthetic gases. Both modules automatically identify and report measurement data to the SC9000/SC9015 Bedside Monitor for display.

The MULTIGas[tm] and MULTIGas+ [tm] modules differ only in the way they measure O_2. The basic MULTIGas Module measures O_2 using a galvanic cell, and calculates average inspiratory values for O_2 (labeled iO_2). The MULTIGas+ incorporates a faster-responding paramagnetic sensor that provides both inspired and expired O_2 measurements (iO_2 and etO_2).

The enhanced software (version VB1.1) is compatible with previously sold versions of the monitor. A retrofit will be offered to the owners of units with previous software versions.

6. Intended Use:

The intended use of the Siemens SC9000/ SC9015 MULTIGas [tm] Module and MULTIGas [tm] + Module is to measure inspiratory and expiratory carbon dioxide, inspiratory and expiratory oxygen, inspiratory and expiratory Nitrous Oxide and anesthetic agents. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce recordings. This device will connect to either the Siemens SIRENET or Infinity (Olympus) network.

7. Table of device similarities and differences to predicate device

	Substantial Equivalence Hewlett Packard Model M1026A Anesthesia Gas Module	SC 9000/9015 Series MULTIGAS [tm] and MULTIGAS+ [tm] Modules
Manufacturer	Hewlett-Packard	Siemens Medical Systems - Electromedical Group
510K Number	K951127	New
Intended Population	Not stated in literature	Adult and Pediatric
Module/Stand-Alone Monitor	Module: Communicates only with HP Anesthesia Component Monitoring System	Module: Communicates only with Siemens SC9000/9015 Bedside Monitors
Displayed Parameters	CO2, N2O, Respiration Rate, Anesthetic Agents	Same
Principle of Operation	Non-dispersive Infra Red	Same
Measuring Methods	sidestream	Same
Waveform Display	Inspired and expired concentrations (in %) plus waveform and trend data	Same
Dimensions HxWxD (mm/in)	80x370x439 / 3.5x14.5x17.3	146x183x451 / 5.7x7.2/17.8
Weight kg / lb	8.2 / 18	7.3 / 16.0

8. Assesment of non-clinical performance data for equivalence: Both the Siemens MULTIGas [tm] Modules and the HP M1026A Anesthesia Gas module employ, internally, the Andros Inc Model 4700 MGM Multi Gas Module as the means for measuring the various gases.

9. Assesment of clinical performance data for equivalence: Not applicable

10. Biocompatability: Not applicable

11. Sterilization: Not applicable

Siemens Medical Systems, Inc.

Electromedical Group

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 1997

Ms. Jacqueline E. M. Emery
Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, Massachusetts 01923

Re: K965062
Siemens SC9000/SC9015 MULTIGas™ and MULTIGas+™ Modules
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: March 25, 1997
Received: March 27, 1997

Dear Ms. Emery:

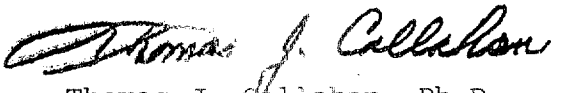
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

Indicated Use Statement

The Siemens SC9000/SC9015 MULTIGas tm and MULTIGas+ tm Modules are indicated for adult and pediatric patient populations in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that these devices are required to measure any one or more of the following parameters:

- Respiration rate
- inspired and expired Carbon Dioxide (CO_2)
- inspired and expired Oxygen (MULTIGas+ only)
- average inspired Oxygen (MULTIGas only)
- inspired and expired gas concentrations of Enflurane, Halothane, Isoflurane, Desflurane, Sevoflurane, and Nitrous Oxide

MRI Compatibility Statement:

The Siemens SC9000/9015 MULTIGas tm and MULTIGas+ tm modules are not intended for use in an MRI magnetic field

PCRND Sign-Off

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

510(k) Number Over-the-Counter use

Prescription use
per 21 CFR 801.109 ✓ OR

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