K964624

SEP 11 1997

510(k) SUMMARY

as required per 807.92(c)

2: Submitter's Name, Address:

Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923
Tel: (508) 750-7500
Fax: (508) 777-3398
Official Correspondent: Robert W. Becker
Contact person for this submission: Jacqueline E. M. Emery or Fred Geheb
Date submission was prepared: October 24, 1996

3: Trade Name, Common Name and Classification Name:

A. Trade Name: Siemens SC9000/ SC9015 Bedside Monitoring System

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

* Pending FDA clearance of 510(K) K962291

4: Predicate Device Identification:
The Siemens SC9000/ SC9015 Bedside Monitoring System with modified Arrhythmia Monitoring is an updated software version of the Siemens SC9000/ SC9015 Bedside Monitoring System. The hardware of the SC9000/SC9015 is unchanged. The modification improves the detection and monitoring of arrhythmia. The Siemens SC9000/SC9015 Bedside Monitoring Systems was granted 510(K) clearance under the following 510(K) numbers:

K946306 - Siemens SC9000/SC9015 Monitor (Original Submission)
K954632 - Siemens SC9000/SC9015 Monitor with etCO_2 Functionality

The following submission is currently awaiting FDA 510(K) clearance:
K962291 - Siemens SC9000/SC9015 Monitor modified with Neonatal Functionality.

5. Device Description
The Siemens SC9000/ SC9015 Bedside Monitoring System with modified Arrhythmia Monitoring is an updated software version of the Siemens SC9000/ SC9015 Bedside Monitoring System. The modification improves the detection and monitoring of arrhythmia. The hardware of the SC9000/SC9015 is unchanged.

6. Intended Use:
The intended use of this device is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia (adult), temperature, cardiac output, arterial oxygen saturation, pulse rate, cardiac output, end-tidal carbon dioxide and (central) apnea. This device will produce visual and aural alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to the Siemens SIRENET or Infinity(Olympus)network.

The SC9000/SC9015 Modified Patient Monitoring System is intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of the parameter Cardiac Output, which is intended for use in the adult and pediatric populations only, and Arrhythmia, which is intended for use in the adult population only.*

Siemens Medical Systems, Inc.

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16 Electronics Avenue
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USA
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Telex: 511958 (Siemensm SD)

7. Table of device similarities and differences to predicate device

	Modified Algorithm	**Predicate Device Algorithm**	*Explanation of the modified version*
Manufacturer	Siemens Medical Systems EMG	same	
Device name	SC9000 with modified arrhythmia algorithm	SC9000	2 leads improve arrhythmia detection
510(K) Number	To be assigned	K946306	
Intended Population	Adult, pediatric and neonatal *	same	Same-application areas. Arrhythmia detection is inactive in the neonatal mode.
Software Revision	VB1.1-W	VA2-W	
Display:	up to 2 leads	same	
Available leads:	I, II, III, aVR, aVF, aVL, V, MCL1, MCL6 (MCL1, MCL6 only with 3-lead set; V, aVR, aVF, aVL only with 5 lead set)	same	
Measuring range:	15 - 300 bpm	same	
Accuracy:	±5 bpm /min. or ± 5% (whichever is greater)	same	
QRS detection: amplitude: duration:	 0.5 - 5.0 mV 40-120 msec	 same 70 - 120 msec	 extended to 40 for neonatal.
Frequency ranges: filter setting = Monitor: filter setting = ESU: filter setting = Off:	 0.5 to 40 Hz 0.5 to 20 Hz 0.05 to 40 Hz	same same same	
Degree of protection against electrical shock	Type CF	same	
Defibrillation protection	In accordance with IEC 6-1-2-27	same	
Arrhythmia Detection:	Yes	same	
Pacer Detection:	Yes	same	
Samples/Sec	250 Samples/Second	100 Samples/Sec	Increased sample rate for improved QRS processing.

** with the exception of the parameter Cardiac Output, which is intended for use in the adult and pediatric populations only, and Arrhythmia, which is intended for use in the adult population only.*

8. Assessment of non-clinical performance data for equivalence:
Currently there are no FDA standards for this device. However, the Siemens SC9000/SC9015 Monitor with modified arrhythmia detection complies with:

AAMI (ECAR - D-94) " Draft: Recommended Practice for Testing and Reporting Performance Results of Ventricular Arrhythmia Detection Algorithms" March 1994.

AAMI (EC13 - 1992) "Cardiac monitors, heart rate meters, and alarms".

FDA "Guidelines for Submitting Data in Support of Pre-market Notification (510(K)) Applications for Arrhythmia Detectors (1990)".

9. Assessment of clinical performance data for equivalence:
Clinical performance is equal to, or surpasses that of the predicate device. The assessment of clinical performance is attached in appendix V.

10. Bio-compatability Data:
Not applicable

11. Sterilization data:
Not applicable

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 11 1997

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

Re: K964624
Siemens SC9000/SC9015 Bedside Monitoring System with Modified Arrhythmia Monitoring
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: March 8, 1997
Received: June 10, 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 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

510(k) Number (if known): K964624

Device Name: Siemens SC9000/SC9015 Bedside Monitoring System with Modified Arrhythmia Monitoring

Indications for Use:

This device is capable of monitoring:

- heart rate
- respiration rate
- invasive pressure
- non-invasive pressure
- arrhythmia
- temperature
- cardiac output
- arterial oxygen saturation
- pulse rate
- cardiac output
- end-tidal carbon dioxide and (central) apnea

This device can be connected to third party devices, Siemens SV300™ ventilator and the Baxter Vigilance™ blood gas/continuous cardiac output monitor. The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. Physicians, Nurses, and Technicians, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition. The device is intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of the parameter Cardiac Output which is intended for use in the adult and pediatric populations only; and Arrhythmia which is intended for use in the adult population only.*

MRI Compatibility Statement:

The Siemens SC9000/SC9015 Series is not compatible for use in an 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 _____