JUN 5 1998

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510(k) NOTIFICATION
SIEMENS SC7000 and SC9000XL INFINITY Modular BedsideMonitors

510(k) SUMMARY
as required per 807.92(c)

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: Jacqueline Emery
Date submission was prepared: February 27, 1998

Trade Name, Common Name and Classification Name:

A. Trade Name:
Siemens SC7000 & SC9000 XL INFINITY Modular Bedside Monitor Series

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

Common Name	Classification Number	Class	Regulation Number
Cardiac monitor	74DRT	II	21 CFR 870.2300
Pulse rate monitor	74BWS	II	21 CFR 870.2300
Pulse oximeter	74DQA	II	21 CFR 870.2700
Breathing Frequency Monitor	73BZQ	II	21 CFR 868.2375
Clinical Electronic Thermometer	80BWX	II	21 CFR 880.2910
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
Arrhythmia detector & Alarm	74DSI	III	21 CFR 870.1025
Medical Cathode-Ray Tube Display	74DXJ	II	21 CFR 870.2450
ST Segment Monitor with Alarm	74MLD	III	21 CFR 870.1025
Non-indwelling Blood Pressure Monitor	74DXN	II	21 CFR 870.1130
End-tidal Carbon-Dioxide Monitor	73CCK	II	21 CFR 868.1400

Predicate Device Identification:
Siemens SC9000/SC9015 Patient Monitoring System, original 510(k) submission K946306.

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Device Description:

The SC 7000 and SC 9000XL modular bedside monitors are enhanced versions of the SC 9000 (predicate device - original submission K946306) and use the same front panel display and user interface as the SC 9000. In addition, the SC 9000 docking station is compatible with the SC 7000 and SC 9000XL for power and communication capabilities.

The SC 7000 (mid-level monitor) and the SC 9000XL (high-end monitor) are additions to the Siemens INFINITY Modular Portable Bedside Monitoring Series. Both the SC7000 and SC 9000 XL utilize the same electronics and software, but with different base configurations and available options.

Intended Use:
The intended use of the SC 7000 and SC 9000XL Bedside Monitoring Series is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, arterial oxygen saturation and pulse rate, cardiac output, central apnea, and ST segment analysis. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to a Siemens R50 Bedside Recorder, either directly or via the Infinity network.

COMPANY CONFIDENTIAL
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510(k) NOTIFICATION
SIEMENS SC7000 and SC9000XL INFINITY Modular Bedside Monitors

Table of Device Similarities and differences to predicate device

	Substantial Equivalent Device	Applicant Siemens Medical Systems	
	Siemens SC9000	Siemens SC 7000	Siemens SC9000 XL
Manufacturer	Siemens	Same	Same
510(k) Number	K946306 (original submission)	To be assigned	
Intended Use	The intended use of this device is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, cardiac output, arterial oxygen saturation, pulse rate, cardiac output, end-tidal carbon dioxide, (central) apnea, and ST Segment Analysis. 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 a Siemens R50 Bedside recorder, either directly or via the Infinity Network.	Same	Same
Intended Population	Adult/Pediatric/Neonatal	Same	Same
Intended Environment	In a healthcare environment where patient care is provided by healthcare professionals.	Same	Same
Display type	Color TFT, 10.4"	Same	Same
Waveforms	Up to 8	Same	Same
Arrhythmia Detection	Basic Enhanced Optional	Same	Same
Modular	Yes	Same	Same
Networking	Standard	Same	Same
NBP	Oscillometric	Same	Same
MIB	Compatible	Same	Same
MultiGas	Compatible	Same	Same
ST	3/7/8 leads	Same	Same
IBP	Up to 8 channels	Same	Same

Assessment of non-clinical performance data for equivalence: See Section U

Assessment of clinical performance data for equivalence: See Section V

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: See Section W

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 5 1998

Ms. Penelope H. Cameron
Regulatory Submissions Manager
Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923

Re: K980882
Siemens SC 7000/SC 9000XL INFINITY Modular Bedside Monitors
Regulatory Class: III (three)
Product Code: DSI
Dated: March 4, 1998
Received: March 9, 1998

Dear Ms. Cameron:

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

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):_____

Device Name: Siemens SC 7000 and SC 9000 XL INFINITY Modular Bedside Monitors

Indications for Use:

The SC 7000 and SC 9000XL INFINITY Modular Bedside monitors are capable of monitoring:

- Heart rate
- Respiration rate
- Invasive pressure
- Non-invasive pressure
- Arrhythmia
- Temperature
- Cardiac output
- Arterial oxygen saturation
- Pulse rate
- End-tidal carbon dioxide
- (central) apnea
- ST segment analysis

With the MultiGas™ and MultiGas+™ modules the SC 7000 and SC 9000XL are capable of measuring:

- Respiration rate
- Inspired and expired Carbon Dioxide (CO2)
- 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.

The SC 7000 and SC 9000XL can interface with third party devices.

The devices are 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 devices are intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of the parameter Cardiac Output and ST Segment Analysis which are 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 SC 7000 and SC 9000XL INFINITY Modular Bedside Monitors are not compatible 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 X 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 K980882