

Special 510(k): Device Modification
Siemens SC 8000 Bedside Monitor

510(k) SUMMARY

NOV 6 1998

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: Penelope H. Greco
 Date submission was prepared: October 9, 1998

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens SC 8000 Bedside Monitor

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
Monitor, Carbon-Dioxide, Cutaneous	73LKD	II	21 CFR 868.2480
Monitor, Oxygen, Cutaneous, for infant not under gas anesthesia	73KLK	II	21 CFR 868.2500

Legally Marketed Device Identification:

Siemens SC 7000/SC9000 XL INFINITY Modular Bedside Monitors, 510(k) submission K982730.

COMPANY CONFIDENTIAL

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16 Electronics Avenue
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 USA

Tel: (978) 907-7500
 Fax: (978) 750-6879
 Telex: 511958 (Siemensm SD)

Special 510(k): Device Modification
Siemens SC 8000 Bedside Monitor

Description of Modification:

The SC 8000 bedside monitor is a modified version of the SC 7000/SC 9000XL INFINITY Modular Bedside Monitors (K982730). The SC 8000 supports all SC 7000 software based options and offers all of the standard I/O connections of the SC 7000 plus interface plate. The hardware has been reengineered as a unit without a display that allows customers the option of providing their own medical-grade display.

Intended Use:

The intended use of the SC 8000 Bedside Monitor is to monitor heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, arterial oxygen saturation, pulse rate, (central) apnea, cardiac output, ST Segment Analysis, 12-lead ST Segment Analysis, and transcutaneous partial pressure of oxygen and transcutaneous carbon dioxide. 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.

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

Assessment of clinical performance data for equivalence: Not applicable

Biocompatibility: Not applicable

Sterilization: Not applicable

Standards and Guidances: See Declaration of Conformity, Section P-1

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Telex: 511958 (Siemensm SD)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

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

Re: K983632
Trade Name: Siemens SC 8000 Bedside Monitor
Regulatory Class: III
Product Code: 74 DSI
Dated: October 14, 1998
Received: October 15, 1998

Dear Ms. 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 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.

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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): _____

Device Name: Siemens SC 8000 Bedside Monitor

Indications for Use:

The SC 8000 Bedside monitor is capable of monitoring:

- Heart rate
- Respiration rate
- Invasive pressure
- Non-invasive pressure
- Arrhythmia
- Temperature
- Cardiac output
- Arterial oxygen saturation
- Pulse rate
- (central) apnea
- ST segment analysis
- 12-Lead ST Segment Analysis
- tcpO2/CO2

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 and ST Segment Analysis which are intended for use in the adult and pediatric populations only; Arrhythmia which is intended for use in the adult population only; and tcpO2/CO2 which is to be used in the neonatal population only.*

MRI Compatibility Statement:

The Siemens SC 8000 Bedside Monitor is not compatible for use in a MRI magnetic field.

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

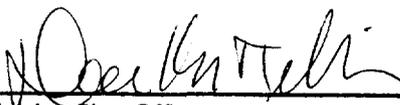
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



 (Division Sign-Off)
 Division of Cardiovascular, Respiratory,
 and Neurological Devices
 510(k) Number K983632