JUL - 8 1998

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

2. 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: December 5, 1997

3. Trade Name, Common Name and Classification Name:

A. Trade Name:
Siemens SC9000/SC9015 Bedside Monitoring System Enhanced with 12-Lead ST Segment Analysis

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

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4. Predicate Device Identification:

Siemens MEGACART™ granted SE (substantial equivalence) under 510(k) file number K915225)

5. Device Description:

The Siemens SC9000/SC9015 Bedside Monitoring System Enhanced with 12-Lead ST Segment Analysis is an updated version of the Siemens SC9000/SC9015 Bedside Monitoring System granted premarket clearance under 510(k) file number K946306 (primary submission).

The system is comprised of the following components:

- MultiMed-12™ ECG pod
- SC9000 with a new, optional processing board and enhanced software
- MultiView WorkStation with enhanced software
- Cardiology Review Station (optional)

A new 12-lead ECG patient cable, the MultiMed-12™ "pod', collects data from the patient and provides raw ECG data to the new SC9000 processing board (code named ARIES).

To enable 12-lead ST processing, the new, optional processing board must be installed in the SC9000 unit. In addition, the SC9000 must have the new software version VC0 installed. The new processing board filters the incoming ECG signals from the MultiMed-12™ ECG pod, down-samples them to 500 samples/s and performs QRS detection. The SC9000 then performs 12-lead ST analysis on the ECG leads provided, using the same algorithm as the predicate device (Siemens Megacart™, K915225) with minor modifications. The SC9000 with VC0 software and the new, optional processing board has the ability to generate ST vector magnitude (STVM) and an ST change magnitude (STCVM) vector.

The SC9000 may be connected to a central station, the MultiView WorkStation (K955059). When the MultiView Workstation is connected to a commercially available LaserPrinter™, ECG reports can be printed. VC0 software needs to be installed in the MultiView WorkStation to enable this functionality. The MultiView WorkStation requires no hardware modifications.

The Cardiology Review Station (CRS), a derivative of a MVWS, receives all available ST complexes and associated measurements from the SC9000, and collects and archives the trend data for review by the user.

6. Intended Use:

To determine the ST Segment of the ECG signal and to compute the deviation of this ST Segment from the iso-electric point (baseline) in a health care environment by health care professionals, i.e. Physicians, Nurses, Technicians.

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7. Table of Device Similarities and differences to predicate device

	Substantial Equivalent Device Siemens Megacart	Applicant Siemens Medical Systems SC9000/SC9015 enhanced with 12 Lead ST Segment Analysis	
Manufacturer	Siemens-Elema	Siemens Medical Systems	
510(k) Number	K915225	To be assigned	
Intended Use	To determine the ST Segment of the ECG signal and to compute the deviation of this ST Segment from the iso-electric point (baseline).	Same	
Intended Population	Adult, Pediatric	Same	
Intended Environment	In the medical clinic or hospital environment for use by physicians, nurses and ECG technicians.	Same	
ST Analysis	Up to 12 ST complexes	Same	
	ST analysis performed on all available leads at 500 s/s	Same	
	Computes ST Vector Magnitude (STVM)	Same	
		Computes Change in ST Vector Magnitude (STCVM)	A mathematical equation that involves no signal processing
ECG Processing	Megacart Algorithm	Same	
	Analog Devices ADSP2101	SC9000 with new processor Board installed	
	12 leads	Same	

8. Assessment of non-clinical performance data for equivalence: Currently there are no FDA standards for this device.

9. Assessment of clinical performance data for equivalence:
Not applicable. Performance was qualified by testing versus a standard clinical database per AAMI recommendations.

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10. Biocompatability:
Not applicable

11. Sterilization:
Not applicable

12. Standards and Guidances:
Currently there are no FDA standards for this device.
"ST Segment Monitor Preliminary Guidance", US Department of Health and Human Services, July 1994.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. David Simard
Siemens Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923

Re: K974698
Siemens SC9000/SC9015 Enhanced with 12-Lead ST Segment Analysis
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: April 10, 1998
Received: April 13, 1998

Dear Mr. Simard:

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,

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 SC9000/SC9015 Bedside Monitoring System Enhanced with 12-Lead ST Segment Analysis

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
- End-tidal carbon dioxide
- (central) apnea
- ST segment analysis

With the MultiGas™ and MultiGas+™ modules the SC9000/SC9015 is 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 SC9000/SC9015 is capable of performing 12-lead ST Segment analysis.

This device can be connected to third party devices: Siemens SV300™ ventilator, the Baxter Vigilance™ blood gas/continuous cardiac output monitor, Puritan Bennett 7200™, Draeger Evita II™, Evita IV™, & Babylog™, and Siemens SV900™ ventilators.

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; and Arrhythmia which is intended for use in the adult population only.*

MRI Compatibility Statement:
The Siemens SC9000/SC9015 Bedside Monitoring System Enhanced with 12-Lead ST Segment Analysis 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 ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Mark Kramer
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K974112

(Optional Format 1-2-96)