K974492

FEB 2 6 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) 750-7500
Fax: (978) 777-3398
Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Jacqueline Emery
Date submission was prepared: November 14, 1997

3. Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens SC6000/ SC6000P Bedside Monitoring Series enhanced with 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
Noninvasive Blood Pressure Monitor	74DXN	II	21 CFR 870.1130
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
ST Segment Monitor with Alarm	74 MLD	III	21 CFR 870.1025
Arrhythmia Detector & Alarm System	74DSI	III	21 CFR 870.1025

2. Predicate Device Identification:

The Siemens 1481 (T) Digital Telemetry System with ST Segment Analysis Option (K951371)

3. Device Description:

The SC 6000 / SC 6000P Bedside Monitoring Series Enhanced with ST Segment Analysis is an updated software version of the SC 6000 / SC 6000P Bedside Monitoring Series. The modification adds software to determine the ST Segment of the ECG signal and to compute the deviation of this ST Segment from the iso-electric point (baseline). This is the same algorithm that is used in the Siemens 1481 (T) Digital Telemetry System with ST Segment Analysis Option (K951371). The hardware of the SC 6000 / SC 6000P (510(k) K944350) is unchanged.

The ST Segment Analysis is not active when the SC 6000/SC 6000P is in the neonatal mode.

The modified software (version VC0) is not compatible with all previously sold versions of the monitor. Therefore, a software upgrade will be offered to the owners of units with previous software revisions. No hardware changes are required for the upgrade.

4. Intended Use:

The intended use of the SC 6000/SC 6000P Bedside Monitoring Series is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia (adult) temperature, arterial oxygen saturation, pulse rate, central apnea, and ST Segment Analysis (adult). The device will produce visual and audible alarms if any of the above parameters vary beyond preset limits and produce timed or alarm recordings.

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
USA
Tel: (978) 907-7500
Fax: (978) 750-6879
Telex: 511958 (Siemensm SD)

Siemens SC6000/SC6000P Portable Bedside Monitoring Series with ST Segment Analysis

	Substantial Equivalent Device Siemens Medical Systems 1481T Digital Telemetry with ST Segment Analysis Option	Applicant Siemens Medical Systems SC 6000/SC 6000P Series Enhanced with ST Segment Analysis	Explanation of the modified version
Intended Use	The intended use of this device is to detect a patient's EKG signals and to transmit this data via radiofrequency to a central monitoring station. At the central monitoring station, cardiac arrhythmias, ST segment deviation values and heart rates are determined. The patient's pulse rate and arterial oxygen saturation values, heart rate values, ST segment deviation values are displayed and visual and aural alarms and recordings are initiated if these parameters vary beyond preset limits.	The intended use of this device is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia (adult only), ST Segment Analysis (adult), temperature, arterial oxygen saturation, pulse rate, and (central) apnea. 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 the Siemens SIRENET or Infinity(Olympus) network	The intended use for the ST Segment Analysis is the same for both the SC6000 and the predicate, 1481T .The devices themselves have different intended uses (patient monitor vs. telemetry system)
Intended Population	Adult	Adult	
Intended Environment	Where patient care is provided by healthcare professionals	Same	
ST Segment deviation measurement accuracy	± 1mm / ±0.1mV	Same	
Leads processed	Any two of I, II, III, V	Any one of I, II, III, V, aVR, aVL, aVF	The SC6000 series measures only one lead and supports augmented leads.
ISO point adjustment range	Complex start to fiducial point	Same	
ISO point default	30 msec before QRS onset	Same .	
ST measurement point adjustment range	Fiducial point to complex end	Same	
ST complex length	900 msec	Same	
Sample Rate	100 samples per second	Same	
Update interval	20 Seconds	15 Seconds	
Alarms	Yes	Same	

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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:
The ST Segment Analysis of the SC6000/SC6000P series patient monitors is equivalent to the ST Segment Analysis of the predicate device.

10. Biocompatability:
Not applicable (Same as original submission)

11. Sterilization:
Not applicable (Same as original submission)

12. Standards and Guidance:
Currently there are no FDA standards for this device. The Siemens Series SC 6000/SC 6000P Bedside Monitoring Series enhanced with ST Segment Analysis complies with:

"Performance Measurements for Algorithms to Detect Transient Ischemic ST Segment Changes", IEEE 1992

"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: **K974492**
Siemens SC6000/SC6000P Bedside Monitoring Series
Enhanced with ST Segment Analysis
Regulatory Class: III (three)
Product Code: 74 MLD
Dated: November 25, 1997
Received: November 28, 1997

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 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): K974492

Device Name: Siemens SC6000 / SC6000P Bedside Monitoring Series enhanced with ST Segment Analysis

Indications for Use:

The SC6000/SC6000P enhanced with ST Segment Analysis is intended to be used in the environment where patient care is provided by Healthcare Professionals, trained in the use of the device, i.e. physicians, nurses, and technicians, who will determine when use of ST Segment Analysis is indicated, based upon their professional assessment of the patient's medical condition.

ST Segment Analysis is intended for use in the adult population.

The SC6000/SC6000P is not for home use.

MRI Compatibility Statement:
The Siemens SC6000 / SC6000P Bedside Monitoring System 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)

(Optional Format 1-2-96)

C. Carey

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

510(k) Number _____