

K970920

29 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: David Simard, Director Quality Assurance and Regulatory Affairs.
Contact person for this submission: Jacqueline E. M. Emery
Date submission was prepared: February 12, 1997

3: Trade Name, Common Name and Classification Number:

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

Siemens Medical Systems, Inc.

Electromedical Group

16 Electronics Avenue
Danvers, MA 01923
USA

Tel: (508) 750-7500
Fax: (508) 777-3398
Telex: 511958 (Siemens SD)

510 (K) Notification

Siemens SC9000/ SC9015 Bedside Monitoring System Enhanced with ST Segment Analysis

4: Predicate Device Identification:

The Siemens SC9000/ SC9015 Bedside Monitoring System enhanced with ST Segment Analysis is an updated software version of the Siemens SC9000/ SC9015 Bedside Monitoring System. 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 etCO₂ Functionality

K962291 Siemens SC9000/SC9015 Monitor modified with Neonatal Functionality

K964624 Siemens SC9000/SC9015 Monitor with modified Arrhythmia Monitoring (Pending) *JK*

The software for the ST Segment Analysis was granted 510(K) clearance under:

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

5. Device Description

The Siemens SC9000/ SC9015 Bedside Monitoring System enhanced with ST Segment Analysis is an updated software version of the Siemens SC9000/ SC9015 Bedside Monitoring System. 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 S-T Segment Analysis Option (K951371). The hardware of the SC9000/SC9015 is unchanged.

The ST Segment Analysis is not active when the Siemens SC9000/SC9015 Monitor is in the neonatal functionality *JK*

The modified software (version VB2) is compatible with previously sold versions of the monitor. A retrofit will be offered to the owners of units with previous software versions. There are no hardware changes required for the upgrade.

6. Intended Use:

The intended use of the Siemens SC9000/ SC9015 Bedside Monitoring System is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, temperature, arrhythmia (adult only), cardiac output (adult only), arterial oxygen saturation, pulse rate, end-tidal carbon dioxide, (central) apnea, and ST segment analysis (adult only). 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.

Siemens Medical Systems, Inc.

Electromedical Group

16 Electronics Avenue
Danvers, MA 01923
USA

Tel: (508) 750-7500
Fax: (508) 777-3398
Telex: 511958 (Siemensm SD)

510 (K) Notification

Siemens SC9000/ SC9015 Bedside Monitoring System Enhanced with ST Segment Analysis

7. Table of device similarities and differences to predicate device..

ST Segment Analysis	Substantially Equivalent Device Siemens Medical Systems 1481T Digital Telemetry Option with ST segment analysis option K951371	Applicant Siemens Medical Systems SC9000/SC9015 enhanced with ST analysis	Explanation of the modified version
Manufacturer	Siemens Medical Systems	Same	
510K number	K951371	To be assigned	
Intended patient population	Adult only	Same	
ST segment deviation measurement accuracy	+/- 1 mm	+/- 0.5 mm	+/- 0.1 mV = 1 mm Improvements made in beat classification (K964624) enable higher accuracy.
Leads processed	I, II, III, aVR, aVL, aVF, V	I, II, III, aVR, aVL, aVF, V, V+, V1 - V6	Depends on cable type connected
Iso point adjustment range	complex start to fiducial point	Same	
Iso point default	QRS onset - 30 msec	QRS onset - 28 msec	Sample rate change necessitated QRS onset point to be changed to be a multiple of 4 msec.
ST measurement point adjustment range	fiducial point to complex end	Same	
measurement point default	QRS offset + 80 msec	Same	
ST complex length	900 msec.	Same	
Sample rate	100 samples/ second	250 samples/sec.	Higher sample rate results in higher fidelity signals with finer resolution for alignment.
Update interval	20 seconds	15 seconds	Improved update rate
Alarms	Yes	Same	

Siemens Medical Systems, Inc.

Electromedical Group

16 Electronics Avenue
Danvers, MA 01923
USATel: (508) 750-7500
Fax: (508) 777-3398
Telex: 511958 (Siemensm SD)

510 (K) Notification

Siemens SC9000/ SC9015 Bedside Monitoring System Enhanced with ST Segment Analysis

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:

NA

Performance was qualified by testing versus a standard clinical patient database per AAMI recommendations

10. Biocompatibility Data: Not applicable

11. Sterilization data: Not applicable

Siemens Medical Systems, Inc.

Electromedical Group

16 Electronics Avenue
Danvers, MA 01923
USA

Tel: (508) 750-7500
Fax: (508) 777-3398
Telex: 511958 (Siemens SD)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

JUL 29 1997

Re: K970920
Siemens SC9000/SC9015 Bedside Monitoring System Enhanced with
ST Segment Analysis (SW Version VB2)
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: May 31, 1997
Received: June 4, 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.

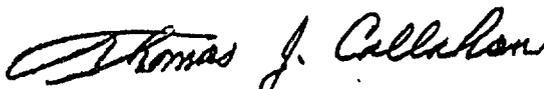
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Ms. Jacqueline Emery

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): K970920

Device Name: Siemens SC9000/SC9015 Bedside Monitoring System Enhanced with ST Segment Analysis

Indications for Use:

This device is capable of monitoring heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia (adult only), temperature, cardiac output (adult only), arterial oxygen saturation, pulse rate, end-tidal carbon dioxide and (central) apnea and ST Segment Analysis (adult only). This device is intended for use by qualified health care providers, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

MRI Compatibility Statement:

The Siemens SC9000/SC9015 Series is not compatible for use in a MRI magnetic field.

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

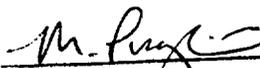
_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



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