

**510(k) Notification****SIEMENS MultiView WorkStation™ Enhanced with Diagnostic Statements (Rest ECG)**

K980625

MAY 19 1998

**510(k) SUMMARY**  
as required per 807.92(c)1. Submitters Name, Address:

Siemens Medical Systems, Inc.  
 Electromedical Systems Group, PCS  
 Danvers, MA 01923  
 Tel: (978) 907-7500  
 Fax: (978) 774-8342  
 Official Correspondent: David Simard, Director  
 Quality Assurance & Regulatory Affairs  
 Contact person for this submission: Jacqueline Emery  
 Date submission was prepared: February 12, 1998

2. Trade Name, Common Name and Classification Name:A. Trade Name:

Siemens MultiView WorkStation™ (MVWS) Enhanced with  
 Diagnostic Statements (Rest ECG)

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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**COMPANY CONFIDENTIAL****Siemens Medical Systems, Inc.**

Electromedical Systems Group, PCS

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 Telex: 511958 (Siemensm SD)

## 510(k) Notification

### SIEMENS MultiView WorkStation™ Enhanced with Diagnostic Statements (Rest ECG)

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3. Predicate Device Identification:

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

4. Device Description:

The Siemens MultiView (SC3000) WorkStation™ enhanced with Diagnostic Statements (Rest ECG) is a modified version of the MultiView (SC3000) WorkStation granted clearance under 510(k) # K955059. This enhancement enables the MultiView WorkStation to interpret diagnostic statements (Rest ECG) and reports of multi-lead ST deviations.

5. Intended Use:

The MultiView WorkStation (MVWS) with Rest ECG collects preprocessed ECG data derived from the SC9000/SC9015 bedside monitor. The data is analyzed by the MVWS to produce reports and possible patient diagnosis for review by the physician (this functionality is currently part of interpretive cardiographs).

This device is intended to be used in an 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.

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6. Table of Device Similarities and differences to predicate device

	<b>Substantial Equivalent Device</b> <b>Siemens Megacart</b>	<b>Applicant</b> <b>Siemens Medical Systems</b> <b>MultiView WorkStation enhanced with</b> <b>Diagnostic Statements (Rest ECG)</b>	<b>Explanation of Differences</b>
<b>Manufacturer</b>	Siemens-Elima	Siemens Medical Systems	
<b>510(k) Number</b>	K915225	To be assigned	
<b>Intended Use</b>	The device determines the ST Segment of the ECG signal and computes the deviation of this ST Segment from the iso-electric point (baseline). The device is suitable for use in resting ECGs and is capable of analyzing the data and providing output with interpretation.	The device is suitable for use in resting ECGs and is capable of analyzing the data and providing output with interpretation.	ST Segment data is processed in the bedside monitor, not the MVWS
<b>Intended Population</b>	Adult, Pediatric	Same	
<b>Intended Environment</b>	In the medical clinic or hospital environment for use by physicians, nurses and ECG technicians.	In an environment where healthcare is provided by healthcare professionals, i.e. doctors, nurses, technicians.	
<b>ST Analysis</b>	Up to 12 ST complexes	Same	
	ST analysis performed on all available leads at 500 s/s	Same	
<b>ECG Processing</b>	Megacart Algorithm	Same	
	Up to 12 leads I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	Same	
<b>Reporting</b>	12 leads ST measurements	Same	
	Interpretation and proposed diagnosis	Same	
	Resting ECG	Same	
	Annotations	Same	

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7. Assessment of non-clinical performance data for equivalence:

Currently there are no FDA standards for this device.

8. Assessment of clinical performance data for equivalence:

Not applicable. Performance was qualified by testing versus a standard clinical database per AAMI recommendations.

9. Biocompatibility:

Not applicable

10. Sterilization:

Not applicable

11. Standards and Guidances:

Currently there are no FDA standards for this device.

“American National Standard for Diagnostic Electrocardiographic Devices”

ANSI/AAMI EC11-R-8-90

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 19 1998

Ms. Jacqueline E. M. Emery  
Siemens Medical Systems, Inc.  
16 Electronics Avenue  
Danvers, MA 01923

Re: K980625  
Siemens MultiView Workstation™ Enhanced with Diagnostic  
Statements  
Regulatory Class: III (three)  
Product Code: 74 DSI  
Dated: February 12, 1998  
Received: February 18, 1998

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 (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, 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): K980625

Device Name: Siemens MultiView WorkStation Enhanced with Diagnostic Statements  
(Rest ECG)

Indications for Use:

This device is capable of connecting to one or more bedside monitors via a network. The device allows the user to monitor the patients connected to these monitors at a central location. The monitoring ability of the device is determined by the bedside monitors. In addition, this device can provide interpretive diagnostic statements and reports when connected to a bedside monitor with ECG monitoring capability.

This device is intended for use with adults and pediatrics in an 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.

**MRI Compatibility Statement:**

The Siemens MultiView WorkStation Enhanced with Diagnostic Statements (Rest ECG) 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)

*M. P...*  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K980625