K972714

510(k) SUMMARY

as required per 807.92(c)

OCT 17 1997

2. Submitters Name, Address

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Tel: (508) 750-7500
Fax: (508) 750-6879

Official Correspondent: David Simard, Director, Quality Assurance & Regulatory Affairs
Contact Person for this submission: Mark Kolnsberg, Senior Clinical Product Manager
Date submission was prepared: July 11, 1997

3. Trade Name, Common Name and Classification Name

A. Trade Name: Siemens MultiView Workstation Infinity Telemetry 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
Pulse rate monitor	74BWS	II	21 CFR 870.2300
Pulse oximeter	74DQA	II	21 CFR 870.2700
Radiofrequency physiological signal transmitter and receiver	74DRG	II	21 CFR 870.2910
Arrhythmia detector & alarm	74DSI	III	21 CFR 870.1025
Medical Cathode-Ray Tube Display	74DXJ	II	21 CFR 870.2450
ST Segment monitor w/alarm	74MLD	III	21 CFR 870.1025

4. Predicate Device Information

Siemens 1481 T Digital Telemetry system granted premarket clearance under 510(k) file number K951371.

5. Device Description

The Siemens MultiView Workstation consists of a PC workstation, up to two CRT displays, keyboard, mouse/trackball input devices and a laser printer.

The Infinity Telemetry System Enhancement adds a CPU/receiver that communicates with the MultiView Workstation PC, an antenna system, a transmitter programming port, radio frequency transmitters and a strip chart recorder. The CPU/receiver can be configured for 1 – 4, 1 – 8, 1 – 12, and 1 – 16 receiver channels for the monitoring of 1 – 16 transmitters. For a more detailed device description refer to Exhibit G, Device Description in this submittal.

6. Intended Use of the Device

The intended use statement for the Infinity Telemetry System Enhancement is to condition and transmit via radiofrequency physiological signals for display and/or measurement.

ECG Ectopic beat detection, arrhythmic rhythm detection and alarm. Measure and alarm audibly and visually for heart rate. Measure and alarm audibly and visually for ECG ST segment elevations or depressions. Measure and alarm audibly and visually for heart arterial oxygen saturation and pulse rate. The device will produce visual and aural alarms if any of the above parameters vary beyond preset limits and produce timed or alarm recordings.

The device is also intended to provide telemetered physiological signals and measurements to the Siemens Infinity (Olympus) Communication Network.

7. Table of device similarities and differences to predicate device

The comparison of intended use and technological features of these devices to other legally marketed devices taken together with the validation results and other information in this submission indicate that these devices are substantially equivalent to legally marketed predicated devices in safety, effectiveness and intended use.

Parameter	***1481 T System***	***MultiView Workstation with Infinity Telemetry Enhancement***	***Explanation of the differences between the predicate and Infinity Telemetry System***
Manufacture	***Siemens***	***Same***	
510(k) Number	K951371	New	
Intended Population	Adult	Adult, Pediatric	The Infinity system's improved ECG performance allows it to be used with a pediatric population.
Display			
No. Waveform Traces	8	16	
Recorder			
Strip Recorder	Yes	Same	
Physiological Parameters			
Parameters	HR, VPB minute rate, % paced, % O2, Pulse rate, S-T deviation	Same	
Alarms	HR, VPB minute rate, arrhythmia events, % paced, % O2, Pulse rate, S-T deviation	Same	
Arrhythmia analysis	Yes	Same	
Event Recall	100 2 ch. 1 minute events/patient	1000 2 ch. 20 second events/patient	Infinity increases # of events stored per patient.
ECG leads displayed Range Accuracy	LI, LII, LIII, V 30 – 300 BPM + / -10% or 5 BPM	LI, LII, LIII, aVF, aVL, AVR, V 15 – 300 BPM + / -5% or 5 BPM	Infinity adds AVF, AVL, AVR ECG leads for display, extends HR range and improves HR accuracy.
Tabular trends	No	Yes	Infinity adds tabular trends for customer preference.
Graphic Trends	Yes	Same	
Radiofrequency Transmission Parameters			
Transmission Scheme	FSK	GMSK	Infinity uses more sophisticated modulation technique for reduced channel spacing.

Tuning ranges of transmitter	174 – 216 MHz. Transmitter tunable over entire 42 MHz range.	174 – 216 MHz, 400 – 460 MHz, 430 – 480 MHz or 512 – 566 MHz Transmitter tunable over entire individual range.	The Infinity RF system is offered in three new operating bands to provide more operating frequencies.
Operator Tuning of Radio Operating Frequency	Externally programmable	Same	
Channel spacing	40 or 50 Khz, even spacing	Same	
Bit rate	10.416 kbits/sec	Same	
Receiver Type	Dual conversion superhetrodyne	Same	
Transmission	RA,LA,LL,RL,V lead wire shields	Same	
Transmitter EKG Parameters			
Input leads	I, II, V	Same	
EKG Dynamic Range	± 5 mV	Same	
Input Offset	± 300 mV max	Same	
EKG sample rate	200 Hz	Same	
A/D resolution	10 bits	Same	
EKG Gain Accuracy	± 5%	Same	
EKG Noise	<40 uV r.t.i.	Same	
Frequency response	0.45 Hz (-2.4 to –3.7 dB) to 40 Hz (-1 to –3dB)	Same	
Pacemaker detection polarity	+ or -	Same	
Pacemaker spike width	0.1 to 2mS	Same	
Pacer spike detection amplitude	± 2.5 - ± 700m V r.t.i.	Same	
Pacer detector 50/60 Hz Rejection	700m V p-p r.t.i.	Same	
EKG input impedance	>25 Mohm at 10 Hz, differential >10 Mohm at 50 Hz, differential	Same	
EKG Analog Output	Yes	Same	
EKG leads with pacer spike detectors	I, II	Same	
Transmitter Electrical & Mechanical Parameters			
Dimensions	116 x 65 x 30 mm	Same	
Weight	160 grams with lithium battery	Same	
Controls	Recorder start: timed & continuous, staff alert	Same	
Indicators	Lead off, low battery	Same	
Water resistant	Yes	Same	
Battery type	9V alkaline or lithium 8.4 V mercury or Zinc Air	Same	
Battery life	2 days minimum with Duracell MN1604	Same	
Shock resistance	Withstands twenty 5 foot drops onto tiled surface with only minor cosmetic blemishes to case	Same	
Defibrillator protection	In accordance with EN 60601-2-27	Same	

8.	Assessment of non-clinical performance data for equivalence:	See Exhibit J
9.	Assessment of clinical performance data for equivalence:	See Exhibit Q
10.	Biocompatibility:	Not applicable
11.	Sterilization:	Not Applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 1997

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

Re: K972714
Siemens MultiView Workstation Infinity Telemetry System Enhancement
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: July 16, 1997
Received: July 21, 1997

Dear Mr. Simard:

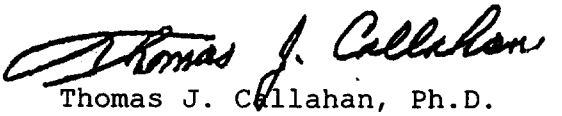
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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, 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): K972714

Device Name: **Siemens MultiView Workstation Infinity Telemetry System Enhancement**

Indications for Use:

Use of the MultiView (SC3000) Workstation Infinity Telemetry System is indicated for adult and pediatric patient populations in an environment where patient care is provided by Healthcare Professionals (Physician, Nurse, Technician) when the professional determines that a device is required to measure and produce visual and audible alarms for any one or more of the following parameters:

- Heart rate
- ECG arrhythmia analysis
- ECG ST segment elevation or depression
- Pulse rate
- Arterial oxygen saturation.

MRI Compatibility Statement:

The MultiView (SC3000) Workstation Infinity Telemetry 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)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972714