Special 510(k): Device Modification
INFINITY MultiView WorkStation Telemetry Modifications

1. 510(k) SUMMARY

DEC 1 8 2002

as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Solutions, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
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Establishment Registration Number: 1220063
Official Correspondent: Connie Hertel, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: December 11, 2002

Trade Name, Common Name and Classification Name:

Trade Name:

INFINITY MultiView WorkStation Telemetry Modification

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
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 with Alarm	74MLD	III	21 CFR 870.1025

Legally Marketed Device Identification:

K972714 INFINITY MultiView WorkStation Telemetry Enhancement
K983980 INFINITY MultiView WorkStation Telemetry Modifications
K003179 INFINITY Telemetry System Modifications

Other Relevant Submissions

K023569 INFINITY MultiView WorkStation Modifications
K012770 INFINITY MicrO2+

Special 510(k): Device Modification
INFINITY MultiView WorkStation Telemetry Modifications

Device Description:

The current conventional 5-lead telemetry transmitter has been modified with a sixth electrode connection.

By adding this sixth electrode connection to the current telemetry, more data is available to clinicians with which to evaluate the patient. This new 6-lead transmitter complies with the Wireless Medical Telemetry Service (WMTS) operating in the dedicated frequency band of 608-614 MHz.

To adapt the current telemetry transmitter/receiver to accommodate the sixth electrode connection, hardware and software modifications were implemented.

The Indications for Use have not changed with the additional electrode connection. Testing has been performed in accordance with internal design control procedures and the FDA Draft Reviewer Guidance, November 1993, and indicates no affect on the safety or efficacy of the INFINITY MVWS Telemetry System.

Intended Use:
Same as K003179

Assessment of non-clinical performance data for equivalence: Section J

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: Section J

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2002

Siemens Medical Solutions, Inc.
c/o Ms. Penelope H. Greco
Regulatory Submissions Manager
16 Electronics Avenue
Danvers, MA 01923

Re: K024108
Trade Name: Siemens INFINITY MultiView WorkStation Telemetry System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: December 11, 2002
Received: December 13, 2002

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K024108

510(k) Number (if known):_____

Device Name: Siemens INFINITY MultiView WorkStation Telemetry System

Indications for Use:

Use of the INFINITY MultiView WorkStation Telemetry System is indicated for adult and pediatric patient populations in an environment where patient care is provided by Healthcare Professionals (Physicians, Nurses, Technicians) 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
- Arterial oxygen saturation
- Pulse rate
- ST segment analysis

MRI Compatibility Statement:
The Infinity MultiView WorkStation 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 X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024108