NOV 4 2002

K023569
page 1 of 2

1. 510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Solutions, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Establishment Registration Number: 1220063
Official Correspondent: Connie Hertel, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: October 21, 2002

Trade Name, Common Name and Classification Name:

A. Trade Name:
INFINITY MultiView WorkStation

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Detector and Alarm, Arrhythmia	DSI	III	870.1025
System, Network and Communication, Physiological Monitors	MSX	II	870.2300

Legally Marketed Device Identification:

K955059 Olympus Communications Network, SC 3000 WorkStation and Remote Display (now referred to as the Infinity Network, MultiView WorkStation and Remote Display)

K003246 Infinity VentViewer (now known as VentCentral)

Device Description:

Introduction

Some features included in the INFINITY MultiView WorkStation VF3 software release are locked options that will be submitted separately.

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The INFINITY MultiView WorkStation (MVWS) software version VF3 modifications include:

Waveform Export
Waveform Export allows the user to export 25 hours of the four full disclosure waveforms to any client device. The export protocol uses Native File System (NFS), a standard file transfer protocol.

Calipers
The release of software version VF3 includes the caliper application, which is an extension of the Full Disclosure database application. The caliper application allows the user to select an 18-second ECG waveform segment from the Full Disclosure database and perform simple caliper measurements.

Selected Strip Report
The Selected Strip Report allows the user to select an area of the topmost channel within Full Disclosure by defining the beginning and ending cursor times.

Second SpO2 and Pulse Parameter Support
Minor software modifications have been implemented to support a second SpO2 and Pulse parameter received from the bedside.

The Indications for Use have not changed with the implementation of Waveform Export, Calipers, or support for a second SpO2 and Pulse parameter received from the bedside. Testing has been performed according to internal design control procedures and indicates no affect on the safety or efficacy of the MultiView WorkStation.

Intended Use:
The intended use of Siemens MultiView WorkStation & INFINITY Network is to act as a communications network, central monitoring device, and remote display for Siemens Patient Monitoring Systems and recorders.

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 E

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K023569
Trade Name: INFINITY MultiView WorkStation
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: October 21, 2002
Received: October 24, 2002

Dear Ms. Greco:

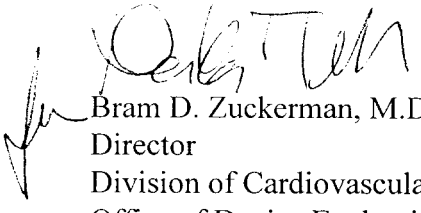
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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

K023569

510(k) Number (if known): K023569

Device Name: INFINITY MultiView WorkStation

Indications for Use:

Siemens INFINITY MultiView WorkStation, INFINITY Network and Remote Display are indicated for use as a central monitoring device, communications network, and remote display for Siemens Patient Monitoring Systems and recorders.

MRI Compatibility Statement:
The MultiView WorkStation and Infinity Network are 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 of Cardiovascular & Respiratory Devices
510(k) Number K023569