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Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date:

July 29, 2003

Submitter:

GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:

Diana M. Thorson
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: (714) 247-4135
Fax: (414) 918-8114

Device: Trade Name:

Unity Network® IS Patient Viewer

Common/Usual Name:

Computer, Information Network Server

Classification Names:

21 CFR 870.2300 System, Network and Communication, Physiological

Predicate Devices:

K020661 Unity Network® IS Patient Viewer

Device Description:

The Unity Network® IS Patient Viewer provides remote access to waveform, parameter data and trend data at a Web browser on a standard personal computer. The server resides on the hospital's intranet and remote access is gained through secured access to the hospital's intranet.

The data relayed from the patient monitors over the Unity® MC network includes patient name, unit and bed name, parameter data, and waveform data monitored by the bedside monitors. The user can view up to nine waveforms from the Unity® MC network as well as the parameter information in near real-time. Neither alarm messages nor parameter status messages are displayed.

The Unity Network® IS Patient Viewer system provides a secondary view of patient information, and is NOT a patient monitoring device. The clinician is instructed to always reference the primary bedside monitor before making any patient care decisions. In the event that data is not available via the Unity Network® IS Patient Viewer, the clinician is instructed to obtain the data from the primary bedside monitor.

Intended Use:

The Unity Network® IS Patient Viewer is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of the Unity Network® IS Patient Viewer is to provide a remote view of physiological parameter data on adult, pediatric and neonatal patients within a hospital or facility providing patient care. The Unity Network® IS Patient Viewer is NOT intended for primary monitoring but is to be used in conjunction with the bedside monitor.

The Unity Network® IS Patient Viewer is intended to provide near-real-time physiological data and graphical trends for all monitors connected to the Unity Network to secure nurse and physician personal computers (local and remote).

Technology:

The Unity Network® IS Patient Viewer system employs the same functional technology as the predicate device. Changes made reflect the recent advancements in wireless technology, offering improved performance and mobility.

Test Summary:

The Unity Network® IS Patient Viewer complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the Unity Network® IS Patient Viewer:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion:

The results of these measurements demonstrated that the Unity Network® IS Patient Viewer is as safe, as effective, and perform as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2003

GE Medical Systems Information Technologies
Ms. Diane M. Thorson
Corporate Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K032346
Trade Name: Unity Network® IS Patient Viewer
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MSX
Dated: July 29, 2003
Received: July 30, 2003

Dear Ms. Thorson:

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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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

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510(k) Number (if known): 510(k) filed on July 29, 2003

Device Name: Unity Network® IS Patient Viewer

Indications for Use:

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(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 K032346