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SEP 17 2003

Section 2 Summary and Certification

510(k) Summary of Safety and Effectiveness

Date:

August 18, 2003

Submitter:

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

Contact Person:

Karen Lunde
Sr. Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: (414) 362-3329
Fax: (414) 918-8114

Device: Trade Name:

Unity Network® Patient Data Server

Common/Usual Name:

Computer, Information Network Server

Classification Names:

21 CFR 870.2300 System, Network and Communication, Physiological

Predicate Device:

K001268 GE Marquette Prism Information Server Applications (MPIS)

Device Description:

The Unity Network® Patient Data Server provides a caregiver the ability to view patient centric events and physiological data that was collected from acquisition devices on the Unity Network prior to the current monitoring session. The Unity Network® Patient Data Server stores at least 500 alarm histories (400 arrhythmia events and 100 ST history events) and at least 72 hours of physiological data per unique patient identifier. Information from the Unity Network® Patient Data Server can be accessed by a GEMS-IT device that implements the Unity Network® Patient Data Server's proprietary data exchange protocol.

The Unity Network® Patient Data Server is a system of hardware and software that operates on standard commercially available server class hardware and interfaces with the Unity Network®. The Unity Network® Patient Data Server system obtains and stores data from devices that are connected and admitted to a monitoring device on the Unity Network® and relays that data to connected clients for viewing. Only clients that are connected to Unity Network® and have access to a proprietary application protocol interface can access the data stored in the Unity Network® Patient Data Server.

The Unity Network® Patient Data Server system provides data to central station monitoring devices, 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® Patient Data Server, the clinician is instructed to obtain the data from the primary bedside monitor.

Intended Use:

The Unity Network® Patient Data Server (PDS) is intended for use under the direct supervision of a licensed healthcare practitioner. The Unity Network® Patient Data Server is intended to provide centralized intermediate term storage of patient centric events and physiological data on adult, pediatric and neonatal patients within a hospital or facility providing patient care. Patient events and physiological data stored at the Unity Network® Patient Data Server can be accessed via any (authorized) device that implements the PDS data exchange protocol. The Unity Network Patient Data Server is NOT intended to be the sole source for patient data and is to be used in conjunction with the data at the bedside monitor and central monitoring station.

Technology:

The Unity Network® Patient Data Server system consists of standard server class hardware purchased from an OEM and loaded with application software developed by GE Medical Systems *Information Technologies*.

The server is connected to two networks: Unity Network® and the hospital's Intranet. The Unity Network® is a currently marketed proprietary network connecting patient monitors. Applications communicate over the Unity Network® using a proprietary protocol in order to obtain or provide data to devices on the network. The hospital's Intranet refers to the existing network within the hospital from which a user can gain access to the product for configuration and servicing.

Test Summary:

The Unity Network® Patient Data Server 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® Patient Data Server:

- 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® Patient Data Server 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

SEP 17 2003

GE Medical Systems Information Technologies
c/o Ms. Karen Lunde
Senior Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K032582
Trade Name: Unity Network® Patient Data Server
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm).
Regulatory Class: Class II (two)
Product Code: MSX
Dated: August 18, 2003
Received: August 21, 2003

Dear Ms. Lunde:

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

510(k) Number (if known): Unknown; 510(k) filed on August 11, 2003

Device Name: Unity Network® Patient Data Server

Indications for Use:

The Unity Network® Patient Data Server (PDS) is intended for use under the direct supervision of a licensed healthcare practitioner. The Unity Network® Patient Data Server is intended to provide centralized intermediate term storage of patient centric events and physiological data on adult, pediatric and neonatal patients within a hospital or facility providing patient care. Patient events and physiological data stored at the Unity Network® Patient Data Server can be accessed via any (authorized) device that implements the PDS data exchange protocol. The Unity Network Patient Data Server is NOT intended to be the sole source for patient data and is to be used in conjunction with the data at the bedside monitor and central monitoring station.

(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 K032582