K053356

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510(k) Summary of Safety and Effectiveness

FEB 10 2006

Date: November 28, 2005

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

Contact Person: Ronald N. Blaski
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA
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Device: Trade Name: CIC Pro Clinical Information Center Central Station

Common/Usual Name: Central Station Monitoring System

Classification Names:

21 CFR 870.2450	Display, Cathode-ray Tube, Medical	DXJ
21 CFR 870.1025	Detector and Alarm, Arrhythmia	DSI

Predicate Device: K032370 Clinical Information Center (CIC) Central Station

Device Description: The CIC Pro Central Station is based on a standard PC platform and provides centralized monitoring of all patients connected to GEMS IT monitors and telemetry transmitters. It may be configured to display up to four real-time waveforms per patient for up to 16 patients.

Controls include the use of a computer mouse, keyboard and optional touch screen for precise touch control. Optional writers for the purpose of graphing waveforms and printing patient information include a 2" Direct Digital Writer or a laser printer.

Intended Use: The CIC Pro Clinical Information Center Central Station is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use is to provide clinicians with adult, pediatric and neonatal patient data in a centralized location within a hospital or clinical environment.

The CIC Pro Central Station is intended to collect information from a network and display this data. This data includes physiological, patient demographic and / or other non-medical information.

Physiological parameters and waveforms from GE Medical Systems *Information Technologies* monitors and telemetry systems can be displayed and printed from the CIC Pro Central Station. Beat to beat patient information for all parameters and waveforms from the bedside and telemetry systems can be displayed.

The CIC Pro Central Station supports the ability to access information from GE Medical Systems *Information Technologies*' products in a web browser format. Additionally, CIC Pro Central Station supports the ability to access patient information collected from the Unity network and stored on a network server.

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Technology: The CIC Pro Central Station employs the same functional technology as the predicate devices.

Test Summary: The CIC Pro platform and its applications comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion: The results of these measurements demonstrated that the CIC Pro Central Station is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2006

GE Medical Systems Information Technologies
c/o Mr. Ronald N. Blaski
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K053356
Trade Name: CIC Pro Clinical Information Center Central Station, Version 5
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II (two)
Product Code: DXJ
Dated: Undated
Received: April 17, 2006

Dear Mr. Blaski:

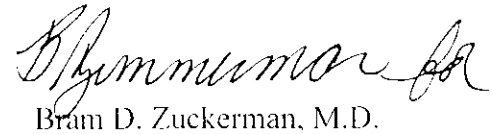
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number: K053356

Device Name: CIC Pro Clinical Information Center Central Station

Indications for Use:

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Prescription Use ___ X ___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053356