

AUG 13 2003

K032370

510(k) Summary of Safety and Effectiveness

Date: July 30, 2003

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

Contact Person: Karen M. Lunde
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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: K001112 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.

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 devices.

Section 3 Proposed Labeling

3.1 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.

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The intended use has not changed as a result of the changes to the CIC Pro Central Station.

3.2 Proposed Operating Instructions

Refer to Appendix A for a copy of changes to the CIC Pro Central Station operating instructions.

3.3 Promotional Material (Device Claims)

Draft promotional information for the CIC Pro Central Station is provided in Appendix B.

3.4 Device and Package Labeling

Device label drawings associated with changes to the device are provided in Appendix C.

Reference the following documents:

	Appendix
Operating Instructions	A
Promotional Material	B
Device Label Drawings	C



AUG 13 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K032370

Trade Name: CIC Pro Clinical Information Center Central Station
Regulation Number: 21 CFR 870.2450, and 21 CFR 870.1025
Regulation Name: Medical cathode-ray tube display, and Arrhythmia detector and alarm.
Regulatory Class: Class II (two), and III (three)
Product Code: DXJ, and DSI
Dated: July 30, 2003
Received: August 1, 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

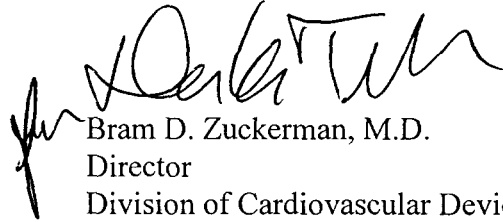
Page 2 – Ms. Karen M. Lunde

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): K032370

Device Name: CIC Pro Clinical Information Center Central Station

Indications For Use:

The CIC Pro Clinical Information Center Central Station is intended to provide clinicians with adult, pediatric and neonatal patient data in a centralized location within a hospital or clinical environment.

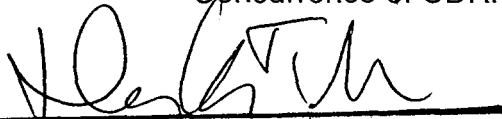
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032370

Prescription Use Only

(Optional Format 3-10-98)