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K062976

Section 5 510(k) Summary of Safety and Effectiveness

MAR 16 2007

Date: September 28, 2006

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

Contact Person: Lisa M. Baumhardt
Regulatory Affairs Program Manager
GE Medical Systems Information Technologies
Phone: (414) 362-3242
Fax: (414) 362-2585

Device: Trade Name: CIC Pro Clinical Information Center

Common/Usual Name: Central Station

Classification Names: The CIC Pro Clinical Information Center is classified as:
21 CFR 870.2450 Display, Cathode-ray Tube, Medical

Predicate Device: K053356 CIC Pro Clinical Information Center

Device Description: The CIC Pro Clinical Information Center is based on a standard PC platform and provides centralized monitoring of all patients connected to GE Medical Systems Information Technologies (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.

CIC Pro Clinical Information Center 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 monitors and telemetry systems can be displayed and printed from the CIC Pro Clinical Information Center central station. Beat to beat patient information for all parameters and waveforms from the bedside and telemetry systems can be displayed.

The CIC Pro Clinical Information Center central station supports the ability to access information from the CIC Pro Clinical Information Center central stations' products in a web browser format. Additionally, the CIC Pro Clinical Information Center central station supports the ability to access patient information collected from the unity network and stored on a network server.

Technology: The CIC Pro Clinical Information Center employs the same functional scientific technology as its predicate devices.

Test Summary: The CIC Pro Clinical Information Center and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket

submission. The following quality assurance measures were applied to the development of the system:

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

Conclusion: The results of these measures demonstrated that the CIC Pro Clinical Information Center 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

MAR 16 2007

GE Medical Systems Information Technologies
c/o Ms. Lisa M. Baumhardt
Regulatory Affairs Program Manager
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K062976
Trade Name: CIC Pro Clinical Information Center
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST measurement and alarm)
Regulatory Class: Class II (two)
Product Code: DSI
Dated: February 14, 2007
Received: February 15, 2007

Dear Ms. Baumhardt:

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 (240) 276-3150 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

510(k) Number (if known): Unknown; 510(k) filed on September 28, 2006

Device Name: CIC Pro Clinical Information Center

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 K062976