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510(k) SUMMARY FOR
GE View Applications

K991629

I. System Sponsor

A. Sponsor's Name and Address

Larry Kroger
Environmental, Health & Safety
GE Medical Systems
P.O. Box 414
Milwaukee, WI 53201
Phone: (414) 544-3894
Fax: (414) 544-3863

II. System Identification

A. Classification Name

Image Processing System

B. Common/Usual Name

Medical Image Viewing Software

C. Trade/Proprietary Name of the System

GE View Applications (GE Viewing Stations and GE Extended Viewing Station)

D. Classification

Regulatory Class: II (two); 21 C.F.R. § 892.2050
Classification Panel: Radiology
Product code: LLZ

III. Predicate Device

General Electric Medical Systems - GE Advantage Review Remote Workstation, K936179. (Cleared as the WinRad Teleradiology System by Line Imaging Systems.)

General Electric Medical Systems - GE Advantage Windows Diagnostic Review Workstation, K960613.

IV. Device Description

GE View Applications is medical image viewing software that consists of two products: the GE Viewing Station and the GE Extended Viewing Station. GE View Applications is a two-dimensional ("2D") review application software for a PC/WIN platform that allows a user to select, send, receive, display, and review of patient image data using the DICOM communication standard. DICOM images can be displayed from any of the following modalities: computed tomography ("CT"); magnetic resonance ("MR"); x-ray ("XR") (XA, R/F); nuclear medicine ("NM"); ultra sound ("US"); computed radiography ("CR"); and modalities that generate secondary capture ("SC") images. GE View Applications can be installed on a PC in the hospital on a local area network ("LAN") or wide area network ("WAN") and includes teleradiology, connectivity, and display features.

V. Intended Use

GE View Applications allows a user to select, send, receive, and review DICOM images from modalities, such as CT, MR, XR, CR, and modalities that generate SC images. GE View Applications is intended to meet different application requirements ranging from simple medical image viewing on the physician's desktop, clinical image review (e.g., in the ICU).

VI. Substantial Equivalence Comparison

GE View Applications is a medical image viewing software device that is substantially equivalent to medical image viewing software devices previously-cleared and currently marketed by GE Medical Systems ("GEMS"). GE View Applications has the same intended use as GE Advantage Review Remote Workstation ("ARR") and the GE Advantage Windows Diagnostic Review Workstation ("AWDR"). GE View Applications is based on, and contains many of the features that were previously-cleared in GE ARR and three features that were previously-cleared in GE AWDR. This device contains one new feature, DICOM CD-Reader. GE View Applications' system requirements also resemble

those in GE ARR and GE AWDR; however, the system has been upgraded to take advantage of currently technology (more memory, higher speed processor, etc.).

VII. Performance Data

System design verification tests have been conducted to assure conformance with the design specifications. Validation testing will be conducted according to the validation test plan and procedures.

VIII. Conclusions

GE View Applications is substantially equivalent to GEMS' previously-cleared GE ARR and GE AWDR Workstations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG -2 1999

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
General Electric Medical Systems, Inc.
P.O. Box 414
Milwaukee, Wisconsin 53201

Re: K991629
GE View Applications (GE Viewing Station and GE Extended Viewing)
Dated: May 7, 1999
Received: May 11, 1999
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991629

Device Name: GE View Applications (GE Viewing Station and GE Extended Viewing Station)

Indications for Use:

GE View Applications is a medical image viewing software device that allows a user to select, send, receive, and review DICOM images from modalities, such as computed tomography ("CT"), magnetic resonance ("MR"), x-ray ("XR"), nuclear medicine ("NM"), ultra sound ("US"), computed radiography ("CR"), and modalities that generate secondary capture ("SC") images. GE View Applications is intended to meet different application requirements ranging from simple medical image viewing on the physician's desktop to clinical image review (e.g., in the ICU).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991629

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)