K972399

SEP 23 1997

GE Medical Systems

Summary of Safety & Effectiveness

This 510(k) summary of safety and effectiveness is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
(414) 544-3894
Summary prepared 24 June 1997

Product Identification:
Name: Advantage Windows Volume Rendering Option
Manufacturer: General Electric Medical Systems
16800 W. Ryerson Road
New Berlin, WI 53151

Marketed Devices: The Advantage Windows Volume Rendering Option is substantially equivalent to the currently marketed Advantage Windows 3D (K923077), Advantage Windows 3D with Navigator Option (K954355), and Advantage CT (9800 Quick) 3D (K871859)

Indications for Use: Advantage Windows Volume Rendering Option is intended to provide fast, easy volume visualization of three dimensional structures imaged with a computed tomography (CT) or magnetic resonance (MR) system. It is dedicated to clinical and diagnostic applications in radiology, surgery, and treatment planning. It runs on Advantage Windows independent workstations

Device Description: Design: The device is a software package to be used on the same software platform as used for Advantage Windows 3D (VoxTool) and will operate on the Advantage Windows Operating System. The workstation hardware required for operation will be the Sun Sparc20, Mod 40, or higher. The images used to provide these 3D reconstructions can be captured by any CT or MR system and transferred to Advantage Windows workstation by DICOM or Ethernet.

Energy Source and Exposure Levels: There is no energy source associated with this package in and of itself. However, the energy source used to make the image being analyzed is the same used to take standard CT or MR diagnostic images.

Principals of Operation: The same as Advantage Windows 3D.
Features: To provide translucent 3D models of areas of interest selected by the operator.
Accessories: None

Adverse Effects on Health: The package itself will not have any adverse affects on health. This tool reconstructs and displays a translucent 3D model of a region of interest selected by the operator. The selection of the region of interest is up to the operator who can choose to accept or reject the region selected.

Conclusions: The Advantage Windows Volume Rendering Option enhances the current Advantage Windows 3D package by providing showing depth and position of overlapping structures. It is substantially equivalent to the Advantage Windows 3D package in design, construction, principle of operation, and features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1997

Larry A. Kroger, Ph.D.
Regulatory Program Manager
GE Medical Systems
P.O. Box 414
Milwaukee, WI 53201

Re: K972399
Advantage Windows Volume Rendering Option
(CT/MR Accessory)
Dated: June 24, 1997
Received: June 26, 1997
Regulatory Class: II
21 CFR 892.1750/Procode: 90 JAK
21 CFR 892.1000/Procode: 90 LNH

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
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):

Device Name: Advantage Windows Volume Rendering Option

Indications For Use:

The Advantage Windows Volume Rendering Option is intended to provide volume visualization of three dimensional structures imaged with computed tomography (CT), or magnetic resonance (MR). It reconstructs and displays translucent 3D models to be used for diagnosis confidence or planning surgical treatment. The images are reconstructed and displayed on the CT/MR Advantage Windows Diagnostic Workstation (K913770).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use_____
(Per 21 CFR 801-109)

David A. Segmon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972399