



K97 4715

JUL 6 1998

GE Medical
Systems

P.O. Box 414, W-709
Milwaukee, WI 53201 USA

ADVANTAGE 3D XR SUMMARY OF SAFETY AND EFFECTIVENESS

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

Identification of Submitter:

Larry A. Kroger, Ph.D.
Senior Manager of Regulatory Programs
Telephone: (414) 544-3894
Date Prepared: December 5, 1997

Identification of Product:

Name : Advantage 3D XR
Manufacturer : General Electric Medical Systems
283, rue de la Miniere
78533 Buc Cedex, FRANCE
Distributor : General Electric Medical Systems, Milwaukee, WI

Marketed Devices:

The Advantage 3D XR is substantially equivalent to the device listed below:

Model: Advantage Windows 3D with Navigator Option
Manufacturer: General Electric Medical Systems
510(k) #: K954355

Device Description:

The Advantage 3D XR is an X-ray imaging software option that allows the interactive display of a structure from any point of view. This is accomplished by constructing a 3D model from images taken during a single Digital Subtracted Angiography (DSA) rotation (200 degrees). A spin acquisition is performed with an LC gantry system using a specific mode (predefined start and stop positions). The data is available for diagnosis on the acquisition system and may be sent to the Advantage Windows workstation. Within 10 minutes, a 3D construction of the vasculature is available and the Navigator software package (K954355) is used to interactively create views of this object. The software allows the ability to make measurements (length and volume) on the 3D structure. The gantry angles for each view are displayed and the physician may use them to make a DSA acquisition on the patient to get an optimized 2d image of the desired viewpoint.



Indications for Use :

The Advantage 3D XR is an X-ray imaging software option that offers the ability to construct a 3D model from images taken during a single DSA rotational angiography. The product is optimized for neuro-angiographic cases.

Comparison with Predicate:

The Advantage 3D XR option allows 3D construction of X-ray images similar to 3D images created with CT/MR images.

Summary of studies :

The Advantage 3D XR option has been successfully validated :

- using a device called a morphometer that consists of an X-ray tube mounted on a CT gantry to acquire views at multiple angles. Two morphometer's have been built and installed on two clinical sites: Hopital Ponchaillou, Rennes, France and HCL, Lyon, France. More than 200 examinations have been done and medical publications on the obtained results are available in Attachment #9.
- using an LC angiographic system gantry. Two experimental clinical sites: Hopital pontchaillou, Rennes, France and CHU Saint-Julien, France have been running for a year and have performed 250 examinations. A publication from Pr Picard, CHU Saint-Julien, France is available in Attachment #9.

Conclusions :

The Advantage 3D XR option provides 3D information from an X-ray spin sequence. The potential hazards (wrong measurements, misdiagnosis) are controlled by a risk management plan including :

- a Hazard Analysis
- a Software Development and Validation Process
- external validations of the algorithms by different research hospitals to assess the validity of the 3D information.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Larry A. Kroger, Ph.D.
Senior, Regulatory Program Manager
GE Medical Systems
P.O. Box 414
Milwaukee, WI 53201Re: K974715
Advantage 3D XR (3D Image Processing Software)
Dated: June 6, 1998
Received: June 17, 1998
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

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 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,

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): K974715

Device Name: Advantage 3D XR

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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
(Per 21 CFR 801-109)

OR Over-The-Counter Use _____

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974715