K983256

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

DEC 15 1998

ADVANTAGE WINDOWS FUSION
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 Regulatory Program Manager
Telephone: (414) 544-3894
Date Prepared: September 15, 1997 (revised December 11, 1998)

Identification of Product:

Name :	Advantage Windows Fusion
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 Windows Fusion is substantially equivalent to the device listed below:

Model:	Fusion and Registration feature of Advance Analysis Software
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K941223

Device Description:

Advantage Windows Fusion is a software option for the Advantage Windows Workstation that provides easy comparison of three dimensional (3D) images from computed tomography (CT) and magnetic resonance (MR). It allows 3D registration between two volumetric acquisitions, which may come from different acquisition modalities (CT / MR).

Application examples include:

- use of previously recorded diagnostic information from follow-up studies.
- combination of CT and MR for better volume definition.
- definition of a volume of interest within one patient model, with automatic report in the other model..
- fusion of functional and anatomical images.
- medical education.
- better communication of clinical results to referring physicians.

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Indications for Use :

Advantage Windows Fusion provides an easy means for comparison of three dimensional (3D) images from computed tomography (CT) and magnetic resonance (MR). It allows 3D registration between two volumetric acquisitions, which may come from different acquisition modalities (CT/MR), for use in diagnostic radiology or radiation therapy planning.

Comparison with Predicate:

The Advantage Windows Fusion option allows comparison of 3D images similar to the comparison of 2D images performed with the Fusion and Registration feature of the Advanced Analysis software. This product provides 3D composite images comparable to the 2D composite images produced by the predicate device .

Summary of studies :

The AW Fusion option will be fully verified/validated per the program test plans

Conclusions :

The Advantage Windows Fusion option provides 3D information that allows comparison of volumetric acquisitions from different studies and modalities. The potential hazards are controlled by a risk management plan including:

- a Hazard Analysis/Risk Management Summary
- a Software Development and Validation Process
- a Software Verification Plan

This product provides images comparable to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 1998

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
P.O. Box 414 , W-709
Milwaukee, WI 53201

Re: K983256
Advantage Windows (AW) Fusion
Dated: September 15, 1998
Received: September 16, 1998
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):

Device Name: Advantage Windows Fusion

Indications for Use

Advantage Windows Fusion provides an easy means for comparison of three dimensional (3D) images from computed tomography (CT) and magnetic resonance (MR). It allows 3D registration between two volumetric acquisitions, which may come from different acquisition modalities (CT / MR), for use in diagnostic radiology or radiation therapy planning.

(PLESE 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983256