NOV - 8 2005

GE Healthcare

K052995 Page 1 of 2

510(k) 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).

Submitter Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
Tel: (262) 544-3894
Fax: (262) 544-4768
GE Healthcare W-400
3000 North Grandview Blvd.
Waukesha, WI 53188 USA
Date Prepared: July 25, 2005.

PRODUCT IDENTIFICATION

Name: Advantage Workstation 4.3

Classification Name: PACS per 21 CFR 892-2050

Manufacturer : General Electric Medical Systems
283, rue de la Minière
78533 Buc Cedex, FRANCE

Distributor: GE Healthcare, P.O. Box 414, Milwaukee, WI 53210

Marketed Devices The Advantage Workstation is substantially equivalent to the devices listed below:

- Model: Advantage Workstation 4.1, 510(k) # K020483
- Manufacturer: General Electric Medical Systems, Buc, France

- Model: Volume Viewer Plus, 510(k) #K041521
- Manufacturer: General Electric Medical Systems, Buc, France

Device Description:

AW 4.3 is a multi-modality review workstation. It includes one or two color flat panel monitors for image review. The workstation allows for easy review, post processing and filming of DICOM images from a variety of imaging systems. AW 4.3 combines AW 4.1 features with the 2D image display features of the Volume Viewer Plus software option.

K052995
Page 2 of 2

The hardware configuration supported by AW 4.3 includes:

- HP Linux based workstation (xw4000, xw8000 or xw8200)
- One or two 19" LCD monitors
- 1 US QWERTY Keyboard
- 1 three button mouse

Indications for Use:

Advantage Workstation 4.3 is a review station, which allows easy selection, review, processing and filming of multi-modality DICOM images from a variety of diagnostic imaging systems. When interpreted by a trained physician, filmed or displayed images on the AW monitor may be used as a basis for diagnosis, except in the case of mammography images.

Comparison with Predicate:

AW4.3 is substantially equivalent to the predicate devices listed above :

Device Name	FDA Clearance Number
Advantage Workstation 4.1	K020483
Volume Viewer Plus	K041521

Adverse Effects on Health:

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:

Advantage Workstation 4.3 does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the Advantage Workstation 4.3 to be equivalent to those of Advantage Workstation 4.1 and Volume Viewer Plus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2005

GE Healthcare
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Service NA., Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re.: K052995
Trade/Device Name: Advantage Workstation 4.3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and Communication system
Regulatory Class: II
Product Code: LLZ
Dated: October 27, 2005
Received: October 28, 2005

Dear Mr. Lehtonen:

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 registrations, 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advices 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 he Act or any Federal statues 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

GE Healthcare

Indications for Use

510(k) Number (if known): K052995

Device Name: Advantage Workstation 4.3

Indications for Use:

Advantage Workstation 4.3 is a review station, which allows easy selection, review, processing and filming of multi-modality DICOM images from a variety of diagnostic imaging systems. When interpreted by a trained physician, filmed or displayed images on the AW monitor may be used as a basis for diagnosis, except in the case of mammography images.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052995