K081985

SEP 25 2008

GE Medical Systems

AW Server
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.

1. **Identification of submitter:**

Author (Primary contact)	**US Designated Agent (2nd contact)**
Stephen Slavens	Kirsten Schutz
DI Global RA Premarket Director	DI Quality Assurance Director
GE Healthcare	GE Healthcare
3000 N Grandview Blvd, W706	3000 N Grandview Blvd, W706
Waukesha, WI 53188	Waukesha, WI 53188
Tel: 262-548-4992	Tel: 262-312-7117
Fax: 262-548-4710	Fax: 262-544-3141
stephen.slavens@ge.com	kirsten.schutz@ge.com

2. **Identification of Product:**

Device name	AW Server
Classification name	PACS per 21 CFR 892.2050
Owner/Operator	General Electric
Manfacturing site	General Electric Medical Systems SCS 283, Rue de la Minière 78533 BUC Cedex France

3. **Marketed Devices**

AW Server is substantially equivalent to the devices listed below:

Model:	Advantage Workstation 4.3
Manufacturer:	General Electric Medical Systems
510 (k):	K052995
Classification name:	PACS per 21 CFR 892.2050
Regulatory Class:	II
Product Code:	LLZ

Model:	AquariusNET Server
Manufacturer:	TeraRecon, Inc.
510 (k):	K012086
Classification name:	PACS per 21 CFR 892.2050 System, Image processing per 21 CFR 829.2020
Regulatory Class:	II
Product Code:	90-LLZ, 90-LMD

4. Device Description :

AW Server is a medical software system that allows multiple users to remotely access AW applications from compatible computers on a network. The system allows networking, selection, processing and filming of multimodality DICOM images.

Both the client and server software are only for use with off the shelf hardware technology that meets defined minimum specifications.

The device is not intended for diagnosis of mammography images. The device is not intended for diagnosis of lossy compressed images. For other images, trained physicians may use the images as a basis for diagnosis upon ensuring that monitor quality, ambient light conditions and image compression ratios are consistent with clinical application.

AW Server is a software package delivered with off-the-shelf server-class hardware that allows easy selection, review, processing and filming of multiple modality DICOM images from a variety of PC client machines, using LAN or WAN networks. It also allows user selectable loss-less and lossy compression schemes that are used in order to make a trade-off between speed and quality.

AW Server is intended to be used in a manner similar to the current GE Medical Systems AW workstation product. It will be used to create and review diagnostic evidence related to radiology procedures by trained physicians in General Purpose Radiology, Oncology, Cardiology and Neurology clinical areas.

AW Server, like Advantage Workstation 4.3, may be used with a variety of other GE software medical devices, which are cleared by FDA in their own names..

5. Indications for Use

AW Server is a medical software system that allows multiple users to remotely access AW applications from compatible computers on a network. The system allows networking, selection, processing and filming of multimodality DICOM images.

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The device is not intended for diagnosis of mammography images. The device is not intended for diagnosis of lossy compressed images. For other images, trained physicians may use the images as a basis for diagnosis upon ensuring that monitor quality, ambient light conditions and image compression ratios are consistent with clinical application.

6. Comparison with Predicate Device

The functional features of AW Server software package are substantially equivalent to that of the following devices:

Device Name	FDA Clearance Number
Advantage Workstation 4.3	K052995
AquariusNET Server	K012086

7. 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.

8. Conclusions

AW Server does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the AW Server to be equivalent to predicate devices listed in section 6. GE has assessed and tested this device as a software moderate Level of Concern device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2008

GE Medical Systems, LLC
% Mr. Daniel W. Lehtonen
Sr. Staff Engineer – Medical Devices
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K081985
Trade/Device Name: AW Server
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 9, 2008
Received: September 10, 2008

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 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 (PMA), 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 advised 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 the Act or any Federal statutes 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____
Device Name: AW SERVER
Indications for Use:

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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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081985