K031396

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MAY 13 2003

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
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GE Medical Systems W-400
3000 North Grandview Blvd.
Waukesha, WI 53188 USA
Date Prepared: April 7, 2003.

PRODUCT IDENTIFICATION

Name: Advantage Workstation Pasting 1.1

Classification Name: Accessory to Magnetic Resonance Diagnostic Device

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

Distributor: General Electric Medical Systems, Buc, France.

Marketed Devices The AW Pasting 1.1 is substantially equivalent to the devices listed below:

Model:	AW X-Ray Pasting (Leg'Map)
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K973270

Device Description:
The GEMS AW Pasting 1.1 software package is a display option, which provides the convenience of viewing a single image resulting from the automatic pasting of multiple images acquired in different stations of the body.

Indications for Use:
The GEMS AW Pasting 1.1 software package is a display option, which combines a series of MR images acquired in multiple stations of the body into a single image. AW Pasting 1.1 provides the convenience of viewing a single image rather than several images.

Comparison with Predicate:
The functional features of the AW Pasting 1.1 software package are substantially equivalent to that of the following device:

Device Name	FDA Clearance Number
AW X-Ray Pasting (Leg'Map)	K973270

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:
The AW Pasting 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 Pasting 1.1 to be equivalent to those of AW X-Ray Pasting (K973270).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2003

GE Medical Systems-Europe
% Mr. Heinz-Joerg Steneberg
Division Manager Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K031396
Trade/Device Name: Pasting 1.1 Software Option for MRI Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: May 1, 2003
Received: May 2, 2003

Dear Mr. Steneberg:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

K03 1396

General Electric Medical Systems

STATEMENT OF INTENDED USE

Device name: Advantage Workstation Pasting 1.1

Intended Use:

The GEMS AW Pasting 1.1 software package is a display option, which combines a series of MR images acquired in multiple stations of the body into a single image. AW Pasting 1.1 provides the convenience of viewing a single image rather than several images.

(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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031396