

JUN 18 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

Classification Name:	PACS (Picture, Archival and Communications System) Workstations
Common/Usual Name:	PACS (Picture, Archival and Communications System) Workstations
Device Trade Name:	PLATINUM Reading, Review & Analysis Workstation
Classification:	FDA has proposed a classification for PACS (Picture Archiving and Communication System) as Class II in 21CFR 892.2050.
Intended Uses:	All areas
Anatomical Region:	Image Review
Diagnostic Uses:	
Establishment Name and Address:	GE Medical Systems 3000 N. Grandview Blvd. Waukesha, WI 53188
Establishment Registration Number:	2126677
Performance Standards:	No applicable performance standards for this device have been issued under Section 514 of the Federal Food, Drug and Cosmetic Act. However, the video display monitors which are components of the system comply with applicable standards for television receivers and appropriate submissions have been filed with CDRH in accordance with the Radiation Control Health and Safety Act. The ROM components of the system comply with 21CFR, Subchapter J - Radiological Health. All workstation components are evaluated for compliance with Information Technology Equipment Standards (UL 1950/IEC 950) by a nationally recognized testing laboratory (NRTL) and so Listed. The device also complies with the standard for EMC - IEC 60601-1-2.

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use. It includes indications for use and cautions. This information assures safe and effective use of the device.

Substantial Equivalence:

The PLATINUM Reading, Review & Analysis Workstation is a medical image display workstation intended to assist radiologists in making diagnoses. The intended use and technological characteristics are similar to the GE Medical Systems PACS Image Display Workstations, Image Acquisition Workstations, and Network Storage Products, GE Medical Systems PACS LiteBox, GE Medical Systems Advantage Windows Review Workstation, and ISG Technologies' ISG Viewing and Reading Stations (VRS), and ISG Silhouette Radiology Application products.



JUN | 8 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Larry A. Kroger, Ph.D.
Regulatory Affairs Program Manager
GE Medical Systems
P.O. Box 414
Milwaukee, WI 53201Re: K981217
Platinum Reading, Review and Analysis
Workstation
Dated: April 2, 1998
Received: April 3, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Dr. Kroger:

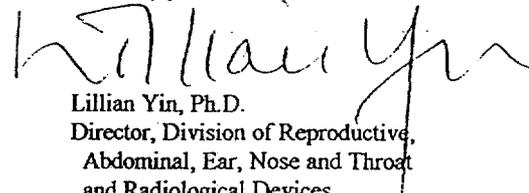
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

