K051678
Page 1 of 2

JUL 1 8 2005

*GE Medical System, F.I. , Haifa*

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87(h)

**Submitter**: GE Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53188

**Contact Person**: Laurence Bigio
Quality, Safety and Regulatory Manager
Telephone: +972-4-856-3663; Fax: +972-4-857-7664

**Date Prepared**: June 24, 2005

**Device Name**: XELERIS 2 PROCESSING AND REVIEW WORKSTATION
System, Image Processing, Radiological, 21 CFR 892.2050, 90-LLZ

**Marketed Device**: GE MEDICAL SYSTEM'S XELERIS PROCESSING AND REVIEW WORKSTATION; 510(k) Number K024137, currently in commercial distribution (first introduced under the name Jupiter).

**Device Description:**

XELERIS 2 PROCESSING AND REVIEW WORKSTATION (Xeleris 2) is a modification of the Xeleris (initially submitted under the name JUPITER PROCESSING AND REVIEW WORKSTATION, K024137), which was first introduced and marketed in 2003. Xeleris 2, is a computer workstation software used for the display, processing, filming, archiving, and communication of Emission Tomography and planar images (data) and hybrid imaging. As in Xeleris, it too includes capabilities to perform image corrections based on Attenuation Tomography and motion and to provide registration of anatomical and physiological images. It runs on Microsoft Windows XP based PC workstation (high resolution color monitor, keyboard, mouse, and CD-RW for archiving), an Ethernet network connection and system software. Optional DVD and optical disk archive devices are also available. The system conforms to the following mandatory and voluntary standards:

- 21 CFR Subchapter J – Radiation Standards for Monitors
- IEC 60950 Safety of information technology equipment
- IEC 60601-1-1 Safety requirements for medical electrical systems
- IEC 60601-1-2 Requirements for safety; Electromagnetic Compatibility.
- IEC 60601-1-4-Medical Electrical Equipment - Part 1-4: General Requirements.
- NEMA PS3, DICOM

**Indications for Use:**

The display, processing, archiving, and communication of data acquired by Emission Tomography cameras used in diagnostic radiology, including procedures for planar imaging, whole body imaging, tomographic (SPECT) imaging, positron imaging by coincidence, attenuation correction, and anatomical image registration.

K051678
Page 2 of 2

*GE Medical System, F.I. , Haifa*

**Comparison with Predicate Device:**

The GE XELERIS 2 PROCESSING AND REVIEW WORKSTATION is a modification of, and is comparable and substantially equivalent to the currently marketed GE XELERIS PROCESSING AND REVIEW WORKSTATION (first introduced under the name Jupiter – K024137). This system has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same basic design, construction, and materials, and has the same intended use as the predicate device.

## Summary of Studies:

The device has been evaluated for electrical, mechanical, and radiation safety, and conforms to applicable medical device safety and performance standards.

**Conclusion:**

Intended use and fundamental scientific technology are the same as the legally marketed GE XELERIS PROCESSING AND REVIEW WORKSTATION. The design and development process of the manufacturer conforms to 21 CFR 820, and ISO 9001/EN 46001 and ISO 13485 quality systems. The device conforms to applicable medical device safety and performance standards. Results of the testing and standards conformance described above demonstrate, in the opinion of GE Medical Systems, that the XELERIS 2 PROCESSING AND REVIEW WORKSTATION is substantially equivalent to the currently cleared XELERIS PROCESSING AND REVIEW WORKSTATION- K024137.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2005

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

Re: K051673
Trade/Device Name: XELERIS 2 Processing and Review Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 20, 2005
Received: June 23, 2005

Dear Dr. Kroger:

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 (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 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.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 Medical System, F.I. , Haifa*

STATEMENT OF INTENDED USE

510(k) Number (if known): K051673

Device Name: **XELERIS 2 PROCESSING AND REVIEW WORKSTATION**

## Indications for Use

The display, processing, archiving, and communication of data acquired by Emission Tomography cameras used in diagnostic radiology, including procedures for planar imaging, whole body imaging, tomographic (SPECT) imaging, positron imaging by coincidence, attenuation correction, and anatomical image registration.

(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** K051673