K980169

GE Medical Systems

General Electric Company
P.O. Box 414 Milwaukee, WI 53201

APR 13 1998

510(k) Summary of Safety & 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.
Regulatory Programs Manager
Who may be contacted by telephone at 414-544-3894 or by FAX at 414-544-3863.
Summary prepared 24 December 1997

Product Identification
Name: HiSpeed LX/i, HiSpeed FX/i, and HiSpeed DX/i Family of Systems
Classification Name: Computed Tomography X-ray System

Manufacturer:	GE-YMS 7-127 Asahigaoka 4-Chome Hino-Shi, Tokyo, Japan 191	**Distributor:**	GE Medical Systems 3000 Grandview Waukesha, Wi 53188

Marketed Devices:
The HiSpeed LX/i, HiSpeed FX/i, and HiSpeed DX/i Family of Systems is of comparable type and substantially equivalent to currently marketed Computed Tomography X-ray Systems that comply with the same or equivalent standards and have the same intended uses.

Device Description:
The HiSpeed LX/i, HiSpeed FX/i, and HiSpeed DX/i Family of Systems consists of a gantry, patient table, console, computer and associated accessories.

Materials: Materials and construction are equivalent to the HiSpeed CT/i (K940606) and are compliant with UL 187, IEC 601-1, and 21 CFR Subchapter J.

Design: The System is designed to be a head and whole body CT scanner utilizing a solid state detector, and an intuitive Operator Console with similar features to the HiSpeed CT/i (K940606).

Indications for Use:
The HiSpeed LX/i, HiSpeed FX/i, and HiSpeed DX/i Family of Systems is indicated for head and whole body x-ray computed tomography applications.

Comparison with Predicate:
It is the opinion of GE Medical Systems that the HiSpeed LX/i, HiSpeed FX/i, and HiSpeed DX/i Family of Systems is of a comparable type and substantially equivalent to currently marketed head and whole body x-ray computed tomography systems with respect to design, material composition, energy source, and radiation characteristics.

Adverse Effects on Health:
Potential electrical, mechanical and radiation hazards are identified in a hazard analysis and controlled by:

- System verification and validation to insure performance to specifications, Federal Regulations, and user requirements.
- Adherence to Industry and International Standards. (UL and IEC)

Conclusions:
Use of the HiSpeed LX/i, HiSpeed FX/i, and HiSpeed DX/i Family of Systems does not result in any new potential safety risks and performs as well as or better than devices currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 1998

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

Re: K980169
HiSpeed LX/i, HiSpeed FX/i, and HiSpeed DX/i
Family of Systems
Dated: January 12, 1998
Received: January 13,1 998
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. 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

510(k) Number (if known):

Device Name: HiSpeed LX/i, HiSpeed FX/i, and HiSpeed DX/i Family of Systems

Indications For Use:

The HiSpeed LX/i, HiSpeed FX/i, and HiSpeed DX/i Family of Systems are indicated for head and whole body x-ray computed tomography applications.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980169