JUN 18 1999

K991716

GE Medical Systems

P.O. Box 414
Milwaukee, WI 53201

510(k) SUMMARY OF SAFETY AND EFFECTIVENES

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

Submitter: Larry A. Kroger
Senior Regulatory Programs Manager
who may be contacted at 414-544-3894 or FAX 414-544-3863
Summary prepared May 11, 1999

Device Name: HiSpeed NX/i CT scanner system.
Classification Name: Computed Tomography X-ray System

Manufacturer
GE-YMS
7-127 Asahigaoka 4-Chome
Hino-Shi, Tokyo, Japan 191

Distributor
General Electric Medical Systems
3000 North Grandview Blvd.
Waukesha, WI 53188

Marketed Devices:

The HiSpeed NX/i CT system and HiSpeed options are of comparable type and substantially equivalent to currently marketed computed tomography systems and options that comply with the same or equivalent standards and have the same intended uses.

Device Description:

The HiSpeed NX/i CT system and HiSpeed options consist of a gantry, patient support, operator console, computer and associated accessories.

Materials: All construction and materials are compliant with 21 CFR Subchapter J and IEC 60601-1 and are equivalent to HiSpeed LX/i, FX/i and DX/i (K980169)

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 LX/i, FX/i and DX/i (K980169), the LightSpeed QX/i (K980176) and options of the HiSpeed CT/i (K940606).

Options: SmartView (K973168) and SmartScore (K982004) software options will be available on HiSpeed LX/i, FX/i and DX/i and HiSpeed NX/i systems.

Indications for Use:

HiSpeed NX/i CT system and HiSpeed options are indicated for head and whole body x-ray computed tomography applications.

Comparison with Predicate Device:

It is the opinion of GE Medical Systems that the HiSpeed NX/i CT system and HiSpeed options are of 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. It will comply with the x-ray performance standards of 21 CFR as well as the safety requirements of the IEC 60601-1 series of standards.

Adverse Effects on Health:

Potential electrical, mechanical, fire and radiation hazards are identified in the attached Risk Analysis and controlled by:

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

Conclusions:

Use of the HiSpeed NX/i CT system and HiSpeed options do 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

JUN 18 1999

Larry Kroger
Senior Regulatory Programs Manager
General Electric Medical Systems
P.O. Box 414
Milwaukee, Wisconsin 53201

RE: K991716
HiSpeed NX/i CT Scanner System
Dated: May 18, 1999
Received: May 20, 1999
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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting 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 NX/i CT system and HiSpeed options

Indications For Use:

The HiSpeed NX/i CT system and HiSpeed options are intended 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991716

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)