NOV 0 8 2001

K013561

GE Medical Systems

General Electric Company
PO Box 414, Milwaukee, WI 53201

Page 1 of 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
TEL: 262-544-3894, FAX: 262-544-3863
Summary prepared: October 15, 2001

PRODUCT IDENTIFICATION

Name:	LightSpeed 4.0 CT Scanner System
Classification Name:	Computed Tomography X-ray System
Manufacturer:	General Electric Medical Systems 16800 W. Ryerson Road New Berlin, WI 53151
Distributor:	Same as Manufacturer
Marketed Devices:	The LightSpeed 4.0 CT Scanner System 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 LightSpeed 4.0 CT Scanner System is composed of a gantry, patient table, console, computer, and associated accessories.

Materials: Materials and construction are equivalent to the LightSpeed 3.0 CT Scanner System (K002978) are compliant with UL 2601-1, IEC 60061-1, and 21CFR Subchapter J.

Design: The system is designed to be a head and whole body CT scanner utilizing a new solid state detector, an intuitive Operator Console, and the same tube and similar features to the LightSpeed 3.0 CT Scanner System (K002978), but now capable of imaging 16 slices per rotation. The system will use a new multi-slice detector having thinner detector elements.

K013561
Page 2 of 2

Indications for Use:

The LightSpeed 4.0 CT Scanner System 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 LightSpeed 4.0 CT Scanner System is of a 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 requirements of 21CFR1020.30 and1020.33, as well as the safety requirements of UL2601-1, IEC 60601-1 and collateral standards.

Adverse Effects on Health:

Potential electrical, mechanical and radiation hazards are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence to industry and international standards. (UL/CSA and IEC).

CONCLUSIONS

The LightSpeed 4.0 CT Scanner Systems does not result in any new potential safety risks and performs as well as or better than devices currently on the market. GE considers the LightSpeed 4.0 CT System to be equivalent to other marketed devices with the same indications for use and meeting similar standards.

A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2001

General Electric Medical Systems
% Mr. Reiner Krumme
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K013561
Trade/Device Name: LightSpeed 4.0 CT Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: October 22, 2001
Received: October 26, 2001

Dear Mr. Krumme:

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 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:

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" (21 CFR Part 807.97). 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

NOV 0 8 2001

STATEMENT OF INTENDED USE

K013561

510(k) Number (if known): K013561

Device Name: LightSpeed 4.0 CT Scanner System

Indications For Use:

The LightSpeed 4 CT Scanner System is 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013561