K030420

MAR 1 0 2003

GE Medical Systems
3000 N. Grandvew W-1140
Waukesha, WI 53188

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: John W. Jaeckle
Lead CT Safety and Regulatory Engineer
Telephone: 262-312-7358; Fax: 262-312-7369

Date Prepared: February 7, 2003

Device Name: LightSpeed 5.0 Computed Tomography System.
Computed Tomography X-ray System, 21 CFR 892.1750, 90-JAK

Marketed Device: GE Medical System's LightSpeed 4.0 Computed Tomography System (aka LightSpeed[16]); 510(k) Number K013561, currently in commercial distribution.

Device Description:

The GE LightSpeed 5.0 CT Scanner System is composed of a gantry, patient table, image acquisition hardware and software, an operator console, and associated accessories. Materials and construction are equivalent to the LightSpeed 4.0 CT Scanner System and are compliant with UL2601-1, IEC 60601-1 and associated collateral and particular standards, and applicable sections of 21 CFR Subchapter J.

Indications for Use:

The LightSpeed 5.0 CT Scanner System is indicated for head and whole body X-ray computed tomography applications.

Comparison with Predicate Device:

The GE LightSpeed 5.0 Computed Tomography System is a modification of, and of comparable type and substantially equivalent to the currently marketed GE LightSpeed 4.0 (aka LightSpeed[16]) CT System. It 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 LightSpeed 4.0 CT System. The design and development process of the manufacturer conforms with 21 CFR 820, and ISO 9001/ EN 46001 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 LightSpeed 5.0 CT System is substantially equivalent to the currently cleared LightSpeed 4.0 CT System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2003

Mr. John W. Jaeckle
Lead CT Safety and
Regulatory Engineer
GE Medical Systems
3000 N. Grandview Blvd., W-1140
WAUKESHA WI 53188

Re: K030420
Trade/Device Name: LightSpeed 5.0 CT Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: February 7, 2003
Received: February 10, 2003

Dear Mr. Jaeckle:

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

STATEMENT OF INTENDED USE

510(k) Number (if known): K030420

Device Name: **LightSpeed 5.0 CT System**

Indications for Use

The LightSpeed 5.0 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 K030420