GE Medical Systems

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

K973168

NOV 21 1997

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 21 August 1997

Product Identification
Name: SmartView Option for HiSpeed CT/i

Manufacturer: General Electric Medical Systems
16800 W. Ryerson Road
New Berlin, WI 53151

Distributor: Same as Manufacturer

Marketed Devices:

The SmartView Option for HiSpeed CT/i is of a 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 SmartView Option for HiSpeed CT/i is an x-ray computed tomography scanner based on the HiSpeed CT/i platform consisting of a gantry, patient table, console, computer and associated accessories.

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

Design: The design is essentially the same as the HiSpeed CT/i (K940606) and CT/i with Performix Tube Option (K964746) the difference being that the SmartView option includes an in-room monitor, a hand control, and a footswitch for initiating x-rays. The hand control allows for gantry tilt and table positioning as well as control of viewing of the scans displayed in the room.

Energy Source and Exposure Levels: The energy source and exposure levels are the same as those previously submitted for HiSpeed CT/i and HiSpeed CT/i with Performix Tube Option.

Principals of Operation: The same as HiSpeed CT/i and HiSpeed CT/i with Performix Tube Option.

Summary (cont.)
SmartView Option

Indications for Use:

The SmartView Option for HiSpeed CT/i is indicated for head and whole body x-ray computed tomography applications. This option is a modifications which can be added to the existing family of HiSpeed CT/i Systems. The option provides almost "real time" reconstruction (SmartView) with a display latency of less than one second. An in-room monitor provides an image display with 6 frame/sec display of up to ninety, one second rotation, scans. Controls are provided for the control of the table and gantry by a physician or their assistant during procedures that require imaging.

Comparison with Predicate:

It is the opinion of GE Medical Systems that the SmartView Option for HiSpeed CT/i 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 evaluation to insure performance to specifications and Federal Regulations.
- Adherence to Industry and International Standards. (UL and IEC)

Conclusions:

Use of the SmartView Option for HiSpeed CT/i 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

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Larry A. Kroger, Ph.D.
Regulatory Affairs
Program Manager
GE Medical Systems, Inc.
P.O. Box 414
Milwaukee, WI 53201

Re: K973168
SmartView Option for HiSpeed CT/i
Dated: August 25, 1997
Received: August 25, 1997
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Dr. 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 requirement, 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/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): K973168

Device Name: SmartView Option for HiSpeed CT/i

Indications For Use:

The SmartView Option for HiSpeed CT/i is indicated for head and whole body x-ray computed tomography applications.

The SmartView Option is a "real time" reconstruction with a display latency less than one second. An in-room monitor provides an image display with 6 frame/sec display of ninety, one second rotation, scans. Controls are provided for the control of the table and gantry by a physician or their assistant during procedures that require imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use_____
(Per 21 CFR 801-109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973168