K052434

SEP 27 2005

GE Medical System, F.I. , Haifa
4, Hayozma St. P.O. Box 170 Tirat HaCarmel 30200, ISRAEL

Attachment B:

Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c).

GE Medical System, F.I. , Haifa
4, Hayozma St. P.O. Box 170 Tirat HaCarmel 30200, ISRAEL

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:	Laurence Bigio Quality, Safety and Regulatory Manager Telephone: +972-4-856-3663; Fax: +972-4-857-7664
Date Prepared:	August 25, 2005
Device Name:	**"Hawkeye 4 Option for Dual-Head Variable Angle Gamma Camera"** , Radiological, 21 CFR 892.1200, 90-KPS
Marketed Device:	**"Hawkeye Option for Dual-Head Variable Angle Gamma Camera" -K991841** Radiological, 21 CFR 892.1200, 90-KPS

Device Description:

The "Hawkeye 4 Option" is a modification of the "Hawkeye" option (K991841).
"Hawkeye 4 Option" is a Functional Anatomical Mapping and Attenuation Correction option, designed to be used on SPECT system "GE Quasar Nuclear Medicine System" (K022960 trade name "Infinia"). The X-Ray system consists of an X-ray source, High voltage power supply, collimation assembly, X-ray detection unit for 4- detectors, and data collection and processing SW. The X-ray unit is completely integrated with the Infinia (K022960) gamma camera, using the same acquisition station, patient table, and slip-ring gantry. The "Hawkeye 4 Option" provides additional features to optimize radiation dose to the patient up to 700W.
The "Hawkeye 4 Option" features a multi-slice X-Ray detector, with four 5mm slices and total axial coverage of 20mm. The "Hawkeye 4 Option" also utilizes helical CT scanning to further improve the image quality, shorten the acquisition time, and enhance dose efficiency.
The "Hawkeye 4 Option" provides additional features to optimize radiation dose to the patient using a range of X-ray generator power from 350W to 700W.
The system conforms to the USA regulation covered under
Code of Federal Regulations Title 21 Subchapter J- Radiological Health -21CFR1020.30, 21CFR 1020.33.

Indications for Use:

The Intended use of the device is to produce attenuation- corrected NM Images. The attenuation maps are also displayed with the NM images to facilitate the localization of the NM activity in the patient anatomy.

Comparison with Predicate Device:
The GE "Hawkeye 4 Option for Dual-Head Variable Angle Gamma Camera" is a modification of, and is comparable and substantially equivalent to the currently marketed "Hawkeye Option for Dual-Head Variable Angle Gamma Camera" - K991841 .This system 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 "Hawkeye" option (K991841). The design and development process of the manufacturer conforms to 21 CFR 820, and ISO 9001 and ISO 13485 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 "Hawkeye 4 Option for Dual-Head Variable Angle Gamma Camera" is substantially equivalent to the currently cleared "Hawkeye Option for Dual-Head Variable Angle Gamma Camera" - K991841.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2005

Ms. E. Werner
Safety and Regulatory Engineering
GE Medical Systems
F.I. Haifa
4 Hayozma St., P.O. Box 170
Tirat HaCarmel 30200
ISRAEL

Re: K052434
Trade/Device Name: Hawkeye 4 Option for Dual Head Variable Angle Gamma Camera
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 31, 2005
Received: September 6, 2005

Dear Ms. Werner:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

GE Medical System, F.I. , Haifa
4, Hayozma St. P.O. Box 170 Tirat HaCarmel 30200, ISRAEL

STATEMENT OF INTENDED USE-

510(k) Number (if known): K052434

Device Name: **"Hawkeye 4 Option for Dual Head Variable Angle Gamma Camera "**

Indications for Use

The Intended use of the device is to produce attenuation- corrected NM Images. The attenuation maps are also displayed with the NM images to facilitate the localization of the NM activity in the patient anatomy.

(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 K052434