1C022960

SEP 19 2002

GE Medical Systems

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

10. 510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: GE Quasar System

Establishment Name and Registration Number of Submitter

Name:	ELGEMS Ltd.
Date Prepared:	July 11, 2002, revised August 27, 2002
Registration Number:	9613299
Corresponding Official:	Hemy Neuman, Quality, Safety and Regulatory Manager ELGEMS Ltd. 10 Hayozma St. Tirat Hacarmel 30200, ISRAEL Hemy.neuman@med.ge.com Tel: +972-4-856-3667 Fax: +972-4-857-7664

Device Classification

Classification Code:	90 KPS
Panel Identification:	Radiology
Classification Name:	Emission Computed Tomography System (per 21CFR 892.1200)
Common Name:	Nuclear Medicine Imaging system
Classification Class:	Class II Product

Reason for 510(k) Submission

Modification of legally marketed device.

Identification of Legally Marketed Equivalent Devices

Elscint Apex VariCam - K953801

GE Hawkeye Option for Dual-Head Variable Angle Gamma Camera – K991841

GE CoDe Option; Volumetric Coincidence Detection (CoDe) Imaging System for VariCam (Nuclear Medicine System) – K962100

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2002

GE Medical Systems
c/o Mr. Heinz Joerg Steneberg
Division Manager Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K022960
Trade/Device Name: GE Quasar System
Regulation Number: 21 CFR §892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: August 30, 2002
Received: September 6, 2002

Dear Mr. Steneberg:

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
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): K022960

Device Name: GE Quasar System

Indications for Use

The intended use of the Quasar system is to perform general Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and optional imaging features designed to enhance image quality in Oncolgy, Cardiology, Neurology and other clinical diagnostic imaging applications.

The scanning modes include planar (Static, Multi-gated, Dynamic, Whole body scanning) and tomographic (SPECT , Gated SPECT , Whole body SPECT , Camera based PET - also known as Coincidence Detection). Acquisition types include single and multi-isotope/multi-peak frame/list mode single-photon and positron imaging. Optional imaging-enhancement features include assortment of collimators, gating by physiological signals, real-time automatic body contouring, and CT-based attenuation correction and functional anatomic mapping.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V
(Per 21 CFR 801-109)

OR Over-The-Counter Use_____

David A. Gayron

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022960