K023932

GE Medical Systems

DEC 11 2002

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

Device Name

Proprietary Device Name: GE Photon Energy Recovery (PER) Option

Establishment Name and Registration Number of Submitter

Name: ELGEMS Ltd.
Registration Number: 9613299
Corresponding Official: Hemy Neuman, Quality and Regulatory
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Device Classification

Classification Code: 90 KPS
Panel Identification: Radiology
Classification Name: System, Emission Computed Tomography (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

GE Vision Nuclear Medicine Workstation – K012568

510(k) Summary of Safety and Effectiveness, GE PER Option, Page 2

Device Description

The Photon Energy Recovery (PER) option is a software application for reducing the Compton scatter contribution in nuclear images. This enables scatter correction of single as well as multipeak isotope imaging. In addition it allows for the correction of cross-talk down scatter in simultaneous multi-isotope imaging. The method is based on a spectral deconvolution analysis using iterative recurrent linear regressions on nuclear spectra. These spectra are broken down into multiple energy windows. This submission provides an extension on the PER features of the currently legally marketed device, GE Vision Nuclear Medicine Workstation – K012568.

Description of Change or Modification

The original PER application featured in the predicate device, GE Vision Nuclear Medicine Workstation (K012568), focuses on Compton scatter reduction for improved contrast and better spatial resolution. The new PER application extends this capability for nuclear cameras by enabling gated SPECT acquisition in multi-energy window format, allowing normal GSPECT processing along with PER scatter correction on the summed data.

The following features are included in the PER Option:

- Scatter correction for single isotope Static, SPECT, and Gated scans
- Scatter and cross-talk correction for simultaneous dual and multi-isotope imaging

Intended Use of Device

The Photon Energy Recovery (PER) Option is intended for image quality and quantification improvement by scatter reduction in planar and tomographic nuclear medicine images. This option enables Gated SPECT acquisition in multi-energy window format which allows normal GSPECT processing along with PER scatter correction on the summed data. It can be used for acquisitions of single or multi-peak isotope as well as simultaneous multi-isotope images.

Summary of Studies

Bench and clinical data show that the PER corrected simultaneous dual-isotope images are similar to the conventional single isotope images.

Conclusion

In the opinion of ELGEMS Ltd., the Photon Energy Recovery (PER) Option is substantially equivalent in terms of safety and effectiveness to the PER capabilities featured in the legally marketed GE Vision Nuclear Medicine Workstation (K012568).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2002

ELGEMS, Ltd.
% Mr. Jeff D. Rongero
Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K023932
Trade/Device Name: GE Photon Energy Recovery (PER) Option
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 85 KPS
Dated: November 25, 2002
Received: November 26, 2002

Dear Mr. Rongero:

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

STATEMENT OF INTENDED USE

510(k) Number (if known): K023932

Device Name: GE Quasar System

Indications for Use

The Photon Energy Recovery (PER) Option is intended for image quality and quantification improvement by scatter reduction in planar and tomographic nuclear medicine images. This option enables Gated SPECT acquisition in multi-energy window format which allows normal GSPECT processing along with PER scatter correction on the summed data. It can be used for acquisitions of single or multi-peak isotope as well as simultaneous multi-isotope images.

(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)

David A. Seyrm

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023932