AUG 26 1999

K991841

9. 510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name : Hawkeye Option for Dual-Head Variable Angle Gamma Camera.

Establishment Name and Registration Number of Submitter

Name:	ELGEMS Ltd.
Registration Number:	9613299
Corresponding Official:	Dan Laor ELGEMS Ltd. P.O. Box 170 Tirat Hacarmel 30200, ISRAEL

Device Classification

Classification Code:	90 KPS
Panel Identification:	Radiology
Classification Name:	ECT 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

VTransACT option for the VariCam Gamma Camera - K980959
Advanced Analysis Software: Fusion/Registration and rCBF Autoradiographic Model - K941223/S1

Device Description

The Hawkeye Option is an addition to the Apex VariCam / Millennium VG gamma cameras (K953801). It comprises additional hardware and software to generate corrected NM images for non-uniform attenuation and to facilitate localization of the emission images in the patient anatomy.

Description of Change or Modification

The VariCam (K953801) gamma camera has been modified to accommodate for the Hawkeye transmission subsystem, by including an additional correction map for attenuation, obtained by an X-ray generation and detection system attached to the rotating frame of the gantry.

Intended Use of Device

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.

Summary of Studies

Bench and clinical data show that Hawkeye attenuation-corrected images are more uniform than NM images without attenuation correction. The images also demonstrate the localization capabilities of the Hawkeye.

Conclusion

In the opinion of ELGEMS Ltd., the Hawkeye is substantially equivalent in terms of safety and effectiveness to the VTransACT (K980959) for purposes of attenuation correction, and to the Advanced Analysis Software (K941223/S1) for purposes of facilitating localization of emission activity in the patient anatomy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 1999

Mr. Dan Laor
Quality and Regulatory Affairs
ELGMENS, Ltd.
P.O. Box 170
Tirat Hacarmel 30200
ISRAEL

Re: K991841
Hawkeye Option for Dual-Head
Variable Angle Gamma Camera
Regulatory Class: II (two)
Product Code: 90 KPS
21 CFR 892.1200
Dated: May 28, 1999
Received: May 28, 1999

Dear Mr. Laor:

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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): K991841

Device Name: Hawkeye option for dual head variable angle gamma camera

Indications For Use:

To obtain attenuation corrected emission images and to provide registration of anatomical and physiological images.

(Please do not write below this line - continue on another page if needed)

(Concurrence of CDRH, Office of Device Evaluation (ODE))

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991841

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)