JUN 4 1998

ELGEMS

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K980959

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

Device Name

VTransACT: Attenuation Correction System for the VariCam Gamma Camera.

Establishment Name and Registration Number of Submitter

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

Device Classification

Classification Code: **90 IYX** Panel Identification: **Nuclear Medicine**
Classification Class: **Class II Product**

Reason for 510(k) Submission

Modification of legally marketed device.

Identification of Legally Marketed Equivalent Devices

TransACT option for the Apex CardiaL Gamma Camera - K952674

Device Description

The VTransACT attenuation correction system is an addition to the Apex VariCam and Millennium VG gamma cameras (K953801). It comprises additional hardware and software to generate corrected NM images for non-uniform attenuation.

Description of Change or Modification

The VariCam (K953801) gamma camera has been modified to accommodate for the VTransACT attenuation correction system, by including an additional correction map for attenuation, obtained by two scanning line sources attached to the heads of the camera. This map is used to create an attenuation-corrected image.

Intended Use of Device

The intended use of the device is to produce attenuation-corrected NM images, even when attenuation coefficients are not uniform over the FOV.

Summary of Studies

Bench data and Clinical data show that the VTransACT option for the VariCam delivers more uniform images than regular SPECT without attenuation correction. Comparison to TransACT images shows no significant difference.

Conclusion

In the opinion of ELGEMS Ltd., the VTransACT is substantially equivalent in terms of safety and effectiveness to the TransACT option for the CardiaL (K952674). The VTransACT has the same intended use as the predicate device and no new safety or effectiveness concerns are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 4 1998

Yair Friedman
VP- Quality and Regulatory Affairs
Elgems Ltd.
P.O. Box 170
Tirat Hacarmel 30200
Israel

Re: K980959
VTransACT: Attenuation Correction System
for Dual-Head Variable-Angle Gamma Camera
Dated: March 12, 1998
Received: March 16, 1998
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Friedman:

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 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,

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): UNKNOWN

Device Name: VTransACT: Attenuation Correction System

Indications For Use:

To obtain attenuation corrected Nuclear Medicine images.

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

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

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980959

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