K994167

MAR - 7 2000

ELGEMS

ELGEMS Ltd. • P.O. Box 170 • Tirat Hacarmel 30200 ISRAEL•
TEL: 972-4-8563660 • FAX: 972-4-8577662

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

Device Name

CoDe AC: Attenuation Correction System for the VariCam 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 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

VTransACT option for the Apex VariCam (Millenium VG Gamma Camera) - K980959

Device Description

The CoDe AC 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 Positron Emission Tomography images for non-uniform attenuation.

Description of Change or Modification

The VariCam (K953801) gamma camera has been modified to accommodate for the CoDe AC attenuation correction system, by including an additional correction map for attenuation, obtained by one line of shielded point sources inserted in the septa collimator 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 PET images, even when attenuation coefficients are not uniform over the FOV.

Summary of Studies

Bench data and Clinical data show that the CoDe AC option for the VariCam delivers more uniform images than regular coincidence imaging system without attenuation correction. Comparison to VTransACT images shows no significant difference.

Summary of the Safety

The CoDe AC sealed and shielded source is activated manually, with no need of electro-mechanical shutter. The source exposure is done only during the transmission

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scan in a sequential transmission/emission acquisition. A self-powered LED indicates continuously the status of the sources. The source is well collimated to the opposite detector FOV only. The CoDe AC option is an integral part of the septa collimator and no motion of the device is needed during the scan.

Conclusion

In the opinion of ELGEMS Ltd., the CoDe AC is substantially equivalent in terms of safety and effectiveness to the VTransACT option. The CoDe AC 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

MAR - 7 2000

Lan Laor
VP-Quality and Regulatory Affairs
ELGEMS Ltd.
P.O. Box 170
Tirat Hacarmel 30200
ISRAEL

Re: K994167
CoDe AC: Attenuation Correction System for Dual-Head Variable Angle Gamma Camera with the Coincidence Option (CoDe)
Dated: August 1, 1999
Received: December 9, 1999
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): UNKNOWN K994167

Device Name: CoDe AC : Attenuation Correction System for Dual-Head Variable Angle Gamma Camera with the Coincidence Option (CoDe).

Indication For Use:

To obtain attenuation corrected Positron Emission Tomography (PET) images, by a Gamma Camera.

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

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994167

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