

JUL 13 1998

ELGEMS

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K981352

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

Device Name

VPC-94: High Energy (511 KeV) Collimator for Dual-Head Variable-Angle Gamma Camera.

Establishment Name and Registration Number of Submitter

Name: ELGEMS Ltd.
Registration Number: 9613299
Corresponding Official: Yair Friedman - VP, Quality and Regulatory Affairs
ELGEMS Ltd.
P.O. Box 170
Tirat Hacarmel 30200, ISRAEL

Device Classification

Classification Code: 90 ~~11X~~ KPS Panel Identification: Nuclear Medicine
Classification Class: Class II Product (Radiology)

Reason for 510(k) Submission

Modification of legally marketed device.

Identification of Legally Marketed Equivalent Devices

Dyna Camera 2C - no K number available, pre-amendment device.
The Dyna Camera 2C is a single-head gamma camera. It can be equipped with the 615-211 High Energy Collimator, having an energy range of 44 - 525 KeV.

Device Description

The VPC-94 high-energy (511 KeV) collimators and cart is an option for the Apex VariCam and Millennium VG gamma camera (K953801). It comprises two high-energy collimators and a collimator cart.

Description of Change or Modification

The VPC-94 is equivalent to the Dyna Camera 2C 615-211 apart from the VPC-94 resolution, which is better at a comparable sensitivity, since two detector heads are used for the VariCam instead of one for the Dyna 2C.

Intended Use of Device

The VPC-94 collimators are designed for high-energy (511 KeV) NM imaging, with the Apex VariCam and Millennium VG Dual-Head Variable-Angle Gamma Cameras.

Summary of Studies

Bench data and Clinical data show that the VPC-94 option achieves its intended use.

Conclusion

In the opinion of ELGEMS Ltd., the VPC-94 is substantially equivalent to the Dyna Camera 2C 615-211 high-energy collimator. The VPC has the same intended use as the predicate device and no new safety or effectiveness concerns are raised.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K981352
VPC-94 High Energy (511 KeV) Collimator for
Dual-Head Variable-Angle Gamma
Dated: April 9, 1998
Received: April 14, 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 K981352

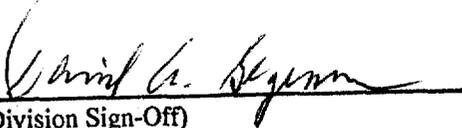
Device Name: VPC-94: High Energy (511 KeV) Collimator for
Dual-Head Variable-Angle Gamma Camera

Indications For Use:

To obtain Nuclear Medicine images based on high-energy photons from an administered positron-emitting radioactive agent in the human body.

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


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981352

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