JAN 18 2000

Gamma Medica™ Instruments
Division of Photon Imaging, Inc.

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: K993813

Submitted by: Bradley E. Patt, PhD
Regulatory Officer
Gamma Medica Instruments
Division of Photon Imaging, Inc.
19355 Business Center Drive, Suite 8
Northridge, CA 91324

Telephone #: (818) 709-2468
Facsimile #: (818) 709-2464

Date Prepared: November 8, 1999

Establishment Registration Number:
Gamma Medica Instruments, Division of Photon Imaging, Inc. is located at 19355 Business Center Drive, Suite 8, Northridge, CA 91324. Applicant has recently submitted a form FDA 2891, and is awaiting receipt of an Establishment Number.

Classification Name:
Scintillation (Gamma) Camera, Class I
21 CFR § 892.1100 (1990)

Common/Usual Name:
Gamma Camera

Proprietary Name:
LumaGEM™ Scintillation Camera

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Northridge, CA 91324
Tel (818) 709-2468
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www.gammamedica.com

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Indications for Use:
The LumaGEM™ scintillation camera is a gamma camera system, which is intended for measuring and imaging the distribution of radionuclides in the human body by means of photon detection. These images are intended to be interpreted by qualified medical personnel.

		Yes	No	Energy Range
A.	Planar Imaging	X		30-300keV
B.	Whole body imaging		X	
C.	Tomographic Imaging (SPECT) for non-positron imaging		X	
D.	Positron coincidence imaging		X	
E.	Positron non-coincidence imaging		X	

Device Description:
The principles of operation and technology incorporated in the LumaGEM™ are equivalent to scintillation gamma cameras which use a combination of a scintillator with photomultiplier tubes as a photon radiation detector. The LumaGEM™ gamma camera includes signal analysis and display equipment, equipment supports and accessories.

Substantial Equivalence Claim:
The LumaGEM™ gamma camera has the same intended use, uses the same principle of radiation detection, and has very similar performance characteristics as the predicate devices; the the **ADAC S315 (Transcam)**, K921296, the **Elscint APEX SPX-4**, the **DIGIRAD Notebook Imager** K961104, the **Siemens Orbiter** and the **SCINTICOR System Seventy Five (SIM-400)**, K885054. The main difference is that the LumaGEM™ camera uses position sensitive photomultiplier tubes, which eliminate a substantial part of the volume and weight of the predicate camera heads and improves substantially the spatial resolution. When compared to the conventional camera system, these changes will either have no effect on the patient's safety, or possibly decrease the risk to the patients, because of the reduced weight of the detector.

Product: **ADAC S315 (Transcam Camera System)**
Manufacturer: ADAC Laboratories
510(k) Number: K921296
Substantial Equivalence Date: 05/28/92

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Product: **APEX SPX-4**
Manufacturer: Elscint NM
510(k) Number: Unknown
Substantial Equivalence Date: Unknown

Product: **Notebook Imager (Model 2020tc)**
Manufacturer: Digirad Corp.
510(k) Number: K961104
Substantial Equivalence Date: 05/28/97
Substantial equivalence notification K961104 is presented as Exhibit H.

Product: **Orbiter**
Manufacturer: Siemens Medical Systems, Inc.
510(k) Number: Unknown
Substantial Equivalence Date: Unknown

Product: **System Seventy Seven**
Manufacturer: Scintcor, Inc.
510(k) Number: K885054
Substantial Equivalence Date: 04/19/89

-end of summary-

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2000

Bradley E. Pratt, Ph.D.
Regulatory Officer
Gamma Medica™ Instruments
Division of Photon Imaging, Inc.
19355 Business Center Dr.
Suite #8
Northridge, CA 91324

Re: K993813
LimaGEM™ Scintillation Camera
Dated: November 8, 1999
Received: November 10, 1999
Regulatory class: I
21 CFR 892.1100/Procode: 90 IYX

Dear Dr. Pratt:

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): K993813

Device Name: LumaGEM™ Scintillation (Gamma) Camera

INDICATIONS FOR USE:

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D.	**Positron coincidence imaging**		X	
E.	**Positron non-coincidence imaging**		X	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993813

Prescription Use ✓ (Per 21 CFR 801.109)

Over-The Counter Use _____

(Optional Format 1-2-96)