SECTION 5
510(k) SUMMARY (CONT.)

510(k) Notification K 111791

GENERAL INFORMATION

Applicant:

SEP 23 2011

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Northridge, CA, 91324 U.S.A.
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Contact Person:

Albert Boniske
Regulatory Consultant
for Gamma Medica-Ideas, Inc.
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Sunnyvale, CA 94085 U.S.A.
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Date Prepared: June 24, 2011

DEVICE INFORMATION

Classification:

21 CFR§892.1100

Product Code:

IYX

Trade Name:

LumaGEM™ Molecular Breast Imaging System

Generic/Common Name:

Scintillation (gamma) camera

PREDICATE DEVICES

Gamma Medica LumaGEM™ Scintillation Camera (K993813)
GE Healthcare Discovery NM 750b Gamma Camera (K102231)

SECTION 5
510(k) SUMMARY (CONT.)

INDICATIONS FOR USE

The LumaGEM™ Molecular Breast Imaging System is intended to measure and image the distribution of radionuclides by means of photon detection in order to aid in the evaluation of lesions in the breast tissue and other small body parts. The LumaGEM™ Molecular Breast Imaging System, when used for breast imaging, is intended to serve as an adjunct to mammography or other primary breast imaging modalities. The LumaGEM™ Molecular Breast Imaging System is indicated for planar scintigraphy in the energy range of 30-300 keV for the detection and display of radioisotope tracer uptake in patients of all ages. The resultant images are intended to be viewed by qualified medical professionals.

PRODUCT DESCRIPTION

The LumaGEM™ Molecular Breast Imaging System is a scintillation camera system, which uses Cadmium Zinc Telluride (CZT) detectors to create an image of radionuclide distribution. The LumaGEM™ Molecular Breast Imaging System is available in a dual-head or single-head configuration and can be used to help identify suspected lesions in breast tissue as an adjunct to standard mammography. The LumaGEM™ Molecular Breast Imaging System is provided with a customized gantry, which allows flexible positioning to facilitate accurate breast imaging, and a workstation to enable image acquisition and analysis functions.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the LumaGEM™ Molecular Breast Imaging System is substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the LumaGEM™ Molecular Breast Imaging System is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench testing was conducted on the LumaGEM™ Molecular Breast Imaging System to support a determination of substantial equivalence to the predicate devices. The following list includes the testing that was performed on the LumaGEM™ Molecular Breast Imaging System:

- Gamma camera verification testing
- System verification testing
- Electrical and mechanical safety testing
- Electromagnetic compatibility testing

SUMMARY

The LumaGEM™ Molecular Breast Imaging System is substantially equivalent to the predicate devices.

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Gamma Medical-Ideas Incorporated
% Mr. Albert Boniske
Senior Manager of Regulatory Affairs
Experian Group LLC – Regulatory Affairs
755 N. Mathilda Avenue, Suite 100
SUNNYVALLE CA 94085

SEP 23 2011

Re: K111791
Trade/Device Name: LumaGEM™ Molecular Breast Imaging System
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: IYX
Dated: August 24, 2011
Received: August 27, 2011

Dear Mr. Boniske:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111791

Device Name: LumaGEM™ Molecular Breast Imaging System

Indications for Use:

The LumaGEM™ Molecular Breast Imaging System is intended to measure and image the distribution of radionuclides by means of photon detection in order to aid in the evaluation of lesions in the breast tissue and other small body parts. The LumaGEM™ Molecular Breast Imaging System, when used for breast imaging, is intended to serve as an adjunct to mammography or other primary breast imaging modalities. The LumaGEM™ Molecular Breast Imaging System is indicated for planar scintigraphy in the energy range of 30-300 keV for the detection and display of radioisotope tracer uptake in patients of all ages. The resultant images are intended to be viewed by qualified medical professionals.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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