K102231

NOV - 3 2010

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	August, 1, 2010
Submitter:	GE Healthcare, GE Medical Systems Israel, Functional Imaging 4 HAYOZMA St TIRAT HACARMEL, 30200, ISRAEL
Primary Contact Person:	Eli Werner Regulatory Affairs Leader GE Healthcare, GE Medical Systems Israel, Functional Imaging +972-4-8563666 +972-4-8577664
Secondary Contact Person:	Laurence Bigio QA site manager GE Healthcare, GE Medical Systems Israel, Functional Imaging +972-4-8563666 +972-4-8577664
Device: Trade Name:	Discovery NM 750b
Common/Usual Name:	Scintillation (gamma) camera
Classification Names:	21CFR 892.1100
Product Code:	90 IYX
Predicate Device(s):	K022960- INFINIA; K993813 LumaGEM scintillation Gamma camera
Device Description:	The Discovery NM 750b is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector. The device may include signal analysis and display equipment, patient and equipment supports, and accessories. The Discovery NM 750b is a high performance and compact planar nuclear imaging system, available in a dual head configuration or a single head configuration. This system is intended to measure and image the distribution of selected single photon emission radioisotopes in the breast and other small body parts in order to aid in the evaluation of lesions.
Intended Use:	The Discovery NM 750b Gamma Camera is intended to measure and image the distribution of selected single photon emission radioisotopes in the human body to aid in the evaluation of lesions. The resultant images are intended to be reviewed by qualified medical professionals. The Discovery NM 750b Gamma Camera is intended for diagnostic imaging of the breast and other small body parts. The Discovery NM 750b Gamma Camera when

used for breast imaging is intended as an adjunct to mammography or other breast imaging modalities (it is not intended for primary screening of the population). The Discovery NM 750b Gamma Camera is indicated for planar and dynamic planar scintigraphy in the energy range 80-200keV for the detection and display of radioisotope tracer uptake in patients of all ages.

Technology: The Discovery NM 750b employs the same fundamental scientific technology as its predicate devices, the Nuclear Medicine SPECT system - Infinia K022960, and the LumaGEM Scintillation Camera K993813. It employs the readout chain and processing software of the Infinia and compact radiation detectors of CZT similar to the LumaGEM. The Discovery NM 750b system comprises one or two CZT Nuclear Medicine detectors mounted an upright positioning gantry.

Determination of Substantial Equivalence: The Discovery NM 750b and its applications is designed to comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

Risk Analysis
Requirements Reviews
Design Reviews
Integration testing (System verification)
Final acceptance testing (Validation)
Performance testing (Verification)
Safety testing (Verification)

Clinical Tests Submitted The 510(k) application does not contain information from GEHC sponsored clinical studies as provided for under 21CFR 54.2(e), and therefore does not require Clinical trials data.

The proposed device has undergone bench testing that was designed to simulate clinical factors.

Conclusion: GE Healthcare considers the Discovery NM 750b to be as safe, as effective, and performance is substantially equivalent to the predicate device(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Mr. Eli Werner
RA Leader
GE Healthcare, GE Medical Systems Israel, Functional Imaging
4 Hayozma Street
Tirat Hacarmel, 30200
ISRAEL

Re: K102231
Trade/Device Name: Discovery NM 750b
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: IYX
Dated: August 1, 2010
Received: August 9, 2010

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Dear Mr. Werner:

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,

David G. Brown, Ph.D.
Acting 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): K102231
Device Name: Discovery NM 750b

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Indications for Use:

The Discovery NM 750b Gamma Camera is intended to measure and image the distribution of selected single photon emission radioisotopes in the human body to aid in the evaluation of lesions. The resultant images are intended to be reviewed by qualified medical professionals. The Discovery NM 750b Gamma Camera is intended for diagnostic imaging of the breast and other small body parts. The Discovery NM 750b Gamma Camera when used for breast imaging is intended as an adjunct to mammography or other breast imaging modalities (it is not intended for primary screening of the population). The Discovery NM 750b Gamma Camera is indicated for planar and dynamic planar scintigraphy in the energy range 80-200keV for the detection and display of radioisotope tracer uptake in patients of all ages.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K102231