



Food and Drug Administration
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Silver Spring, MD 20993-0002

GE Healthcare
% Mr. Efrat Hartog-David
Regulatory Affairs Manager
4 Hayozma Street
Tirat Hacarmel, 30200
ISRAEL

December 12, 2016

Re: K160933
Trade/Device Name: Discovery NM 750b Biopsy
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: IYX
Dated: October 20, 2016
Received: October 27, 2016

Dear Mr. Hartog-David:

This letter corrects our substantially equivalent letter of November 18, 2016. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a faint, large watermark of the FDA logo.

For

Robert Ochs, Ph.D.

Director

Division of Radiological Health

Office of In Vitro Diagnostics

and Radiological Health

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K160933

Device Name
Discovery NM 750b Biopsy

Indications for Use (Describe)

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.

When used with the optional Discovery NM 750b Biopsy system, the Discovery NM 750b is designed to accurately locate, in three dimensions, lesions in the breast using information derived from stereotactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes such as biopsy and pre-surgical localization.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h):

Date: April 1st, 2016

Submitter: GE Medical Systems Israel, Functional Imaging (GE Healthcare)
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Device Trade Name: Discovery NM750b Biopsy

Common / Usual Name: Scintillation (gamma) camera
D750b Biopsy system

Classification Names 21CFR 892.1100

Device Classification Class I

Product Code: 90 IYX

Predicate Device(s): Discovery NM 750b (K102231), GammaLoc System (K082588)

Reference Device: Senographe Stereo (K040125)



Device Description: The Discovery NM 750b Biopsy system is an optional accessory for the Discovery NM 750b gamma camera (K102231) that utilizes stereotactic imaging to help guide invasive procedures. It is intended for 3D lesion localization to provide the physician image guidance for vacuum assisted needle biopsy of breast lesions determined to be suspicious through molecular breast imaging or other imaging.

The Biopsy system uses a pair of CZT “biopsy” detectors with fixed stereotactic positions. These two detectors acquire pair of angulated two-dimensional images that are used in determining the 3D localization of the pre-identified suspicious lesion.

The Discovery NM750b Biopsy system includes hardware and software components, which guides the user throughout the biopsy work-flow. The hardware components enable the use of a variety of off-the-shelf biopsy vacuum needles.

In addition to the hardware components, the biopsy system accessory includes software components which, in part, through the user interface help guide the user stepwise through the biopsy workflow. The Discovery NM 750b Biopsy system is designed to support a variety of commercially available vacuum assisted biopsy devices and needles.

Intended Use: The Discovery NM750b Biopsy system is an optional accessory to the Discovery NM750b Gamma Camera intended for lesion localization in the breast

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.

When used with the optional Discovery NM 750b Biopsy system, the Discovery NM 750b is designed to accurately locate, in three dimensions, lesions in the breast using information derived from stereotactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes such as biopsy and pre-surgical localization.



Technology:

The technological characteristics and corresponding fundamental principles of operation of the imaging unit are identical to that of Discovery NM750b. As discussed above, the Discovery NM750b Biopsy System has the same intended use and similar indications for use to its legally marketed predicate devices, the Discovery NM750b and the GammaLoc system.

The Discovery NM 750b Biopsy accessory's design/operating principle is identical to other well established stereotactic imaging and optics principles. The technological characteristics and corresponding fundamental principles of operation of the Biopsy System are identical or equivalent to that of the GammaLoc system and Senoegrapphe Stereo.

Differences between the Discovery NM 750b Biopsy device and the GammaLoc system include simultaneous vs. sequential acquisition of stereotactic images, the stereotactic angle, lesion verification in X, Y, and existence of additional image viewing tools.

The differences between the Discovery NM 750b Biopsy device and Senography Stereo include simultaneous vs. sequential acquisition of stereotactic images, the stereotactic angle, lesion verification in X, Y, and photon source for image creation.

Stereotactic imaging is based upon acquiring two images taken from different angles of the anatomy of interest. Because of the different acquisition positions, the two 2D images can be used to compute the three -dimensional localization of the lesion. The three-dimensional information is used by the physician to provide guidance for interventional purposes such as biopsy and pre-surgical localization.

Determination of Substantial Equivalence:

Discovery NM750b Biopsy system has completed testing and is certified to conform to the applicable IEC 60601-1 standards.

The device has successfully completed all design control testing per GEHC quality system. No new hazards were identified and no unexpected test results were obtained. The Discovery NM750b Biopsy system was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Software Development Lifecycle



- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

The safety and performance of the Discovery NM750b Biopsy system was demonstrated through full verification testing, additional engineering bench performance testing using phantoms, and simulated clinical use testing performed by physicians using a commercially available breast biopsy phantom and a supporting phantom. This phantom setup had radiotracer-injected simulated lesions against a uniform radioactive background. The activities of the lesions and background were set to be representative of actual clinical use.

The simulated clinical testing performed with the software driven workflow, provided data from cases that represent a broad range of clinically relevant scenarios taken variables such as lesion size, lesion position, gantry orientation, VAD type. Worst case and challenging scenarios were included.

These tests were performed to provide the requisite data to substantiate performance, claims, and ultimately substantial equivalence. The testing demonstrated that the Discovery NM750b Biopsy system performs according to specifications and functions as intended.

Conclusion:

Based on conformance to standards; development under GE Healthcare's quality management system and design controls; successful verification/validation testing; well established stereotactic imaging principles; additional bench performance testing; and the physician-performed clinical simulation testing using an established, commercially available biopsy simulation phantom modified to better represent nuclear medicine characteristics, GE Healthcare believes that the Discovery NM 750b Biopsy system accessory is substantially equivalent to its predicate devices [Discovery NM 750b (K102231) and GammaLoc (K082588)] and reference device (Senographe Stereo (K040125)). Therefore GE concludes that the Discovery NM 750b Biopsy is safe and effective for its intended use