



Food and Drug Administration
10903 New Hampshire Avenue
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GE Healthcare
GE Medical Systems Israel, Functional Imaging
% Mr. George Mashour
Regulatory Affairs Leader
4 Hayozma Street
Tirat Hacarmel, 30200
ISRAEL

January 22, 2016

Re: K153402
Trade/Device Name: Discovery NM/CT 670 CZT
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: November 22, 2015
Received: November 24, 2015

Dear Mr. Mashour:

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 large, faint, light-colored 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 Statement

Discovery NM/CT 670 CZT

Indications for Use

510(k) Number (if known)

K153402

Device Name

Discovery NM/CT 670 CZT

Indications for Use (Describe)

The GE Discovery NM/CT 670 CZT system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and organ function for the evaluation of diseases, trauma, abnormalities, and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The system output can also be used by the physician for staging and restaging of tumors, planning, guiding, and monitoring therapy. The GE Discovery NM/CT 670 CZT system, combining a CZT-based, high energy and spatial resolution, Nuclear Medicine (NM) system and a Computed Tomography (CT) system, is intended to produce:

- NM System: General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The scanning modes include planar mode (Static, Multi-gated, Dynamic and Whole body scanning) and tomographic mode (SPECT, Gated SPECT, Whole body SPECT). The acquisition types include single and multi-isotope/multi peak frame/list mode single-photon imaging. The imaging-enhancement features include, gating by physiological signals, and real-time automatic body contouring.
- CT System: Cross sectional images of the body by computer reconstruction of X-Ray transmission data taken at different angles and planes, including Axial, Cine, Helical, Cardiac, and Gated acquisitions. These images may be obtained with or without contrast. The CT system is indicated for head, whole body, cardiac and vascular X-Ray Computed Tomography applications.
- NM + CT System: Combined, hybrid SPECT and CT protocols, for CT-based SPECT attenuation corrected imaging as well as functional and anatomical mapping imaging (localization, registration and fusion).

The GE Discovery NM/CT 670 CZT system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system may include data and image processing to produce images in a variety of trans-axial and reformatted planes. The images can also be post processed to obtain additional images, imaging planes, analysis results and uptake quantitation. The system may be used for patients of all ages.

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
Discovery NM/CT 670 CZT



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: November 22, 2015

Submitter: GE Medical Systems Israel, Functional Imaging (GE Healthcare)
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Device Trade Name: Discovery NM/CT 670 CZT

Common / Usual Name: Single Photon Emission Computed Tomography (SPECT) & Computed Tomography X-Ray (CT)

Classification Names: 21CFR 892.1200 & 21CFR 892.1750

Product Code: 90 KPS & 90 JAK



Marketed Devices	Discovery NM/CT 670 CZT is a modification to the Discovery NM/CT 670 (K093514) that replaced the NM NaI-based detectors with CZT-based detectors. The detectors are built of the exact same CZT modules that are used in Discovery NM 750b (K102231). The only difference is the number of modules from which the detectors are comprised. All system parts that are not related to the CZT-based detectors remain the same as in Discovery NM/CT 670 (K093514) and have the same functionality and performance.
Predicate Device(s):	Discovery NM/CT 670 (K093514)
Reference Device	Discovery NM 750b (K102231).
Device Description:	<p>Discovery NM/CT 670 CZT is a SPECT-CT system consisting of two back-to-back gantries (i.e. an NM Gantry carrying 2 nuclear detectors and a CT Gantry), patient table, power distribution unit (PDU), operator console with two acquisition systems (i.e. NM and CT), interconnecting cables and associated accessories..</p> <p>The system generates NM images, CT images and enables CT-based attenuation correction and anatomical localization of SPECT images. The NM images are generated through computer reconstruction of data acquired by a CZT-based dual detector NM system that uses a variety of planar and tomographic acquisition types. The CT images are generated by computer reconstruction of data acquired using a commercially available GE Optima CT 540 system.</p>
Intended Use:	The GE Discovery NM/CT 670 CZT system is intended for general Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body. It includes a general purpose Nuclear Medicine system using a variety of scanning modes supported by various acquisition types, and a Computed Tomography system which is intended for enabling attenuation correction and anatomical localization of SPECT images and for standalone head, whole body, cardiac and vascular X-ray Computed Tomography applications.
Indications for Use:	The GE Discovery NM/CT 670 CZT system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and organ function for the evaluation of diseases, trauma, abnormalities, and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The system output can also be used by the physician for staging and restaging of tumors, planning, guiding, and monitoring therapy. The GE Discovery NM/CT 670 CZT system, combining a CZT-based, high energy and spatial resolution, Nuclear Medicine (NM) system and a Computed Tomography (CT) system, is



intended to produce:

- **NM System:** General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and imaging features designed to enhance image quality. The scanning modes include planar mode (Static, Multi-gated, Dynamic and Whole body scanning) and tomographic mode (SPECT, Gated SPECT, Whole body SPECT). The acquisition types include single and multi-isotope/multi peak frame/list mode single-photon imaging. The imaging-enhancement features include, gating by physiological signals, and real-time automatic body contouring.
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Technology:

Discovery NM/CT 670 CZT employs the same fundamental scientific technology as the predicate device and the Discovery NM 750b (K102231) reference device for the CZT-based detectors.

Determination of Substantial Equivalence:

Summary of Non-Clinical Testing:

Discovery NM/CT 670 CZT has completed testing and is in compliance with IEC 60601-1 Ed. 3 and its associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25.

The device has successfully completed all design control testing per our quality system. No new hazards were identified and no



unexpected test results were obtained. The Discovery NM/CT 670 CZT 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)

GE believes Discovery NM/CT 670 CZT system is of comparable type and substantially equivalent to Discovery NM/CT 670. The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Summary of Additional Testing:

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering (i.e. non-clinical testing) and clinical performance testing was performed to provide the requisite data to substantiate performance, claims, and, ultimately substantial equivalence.

Non-Clinical Testing

The additional engineering performance evaluation testing used a variety of test methods and phantoms appropriate for the performance metric/claim that was to be tested and evaluated. Mathematical and physics analysis were performed to demonstrate that each performance metric/claim was successfully verified and substantiated. The areas additionally evaluated for the non-clinical testing included energy resolution, count rate linearity, uniformity and, system resolution and lesion detectability. The lesion detectability evaluation included a model observer study.

Clinical Testing

A clinical study using an investigational Discovery NM/CT 670 CZT and the predicate Discovery NM/CT 670 was performed to



demonstrate the clinical/diagnostic quality by means of sample images and evaluations of them. The sample images were obtained in clinical settings using various clinical protocols for different anatomical procedures. This clinical study was used to obtain the images that were evaluated by 2 nuclear medicine physicians, on a 5-point Likert scale, and then to produce the clinical report included in this 510k

The sample images were collected from 19 subjects at one site in Israel with the approval of appropriate ethics committee and in accordance with Israel's Ministry Health's regulation of such clinical investigations. The study was designed and performed run in accordance with applicable GE Healthcare quality system procedures.

The images were evaluated for image quality and image resolution by 2 experienced and qualified Nuclear Medicine physicians using a 5 point Likert scale. The result of the evaluations showed that the average overall image quality (IQ, resolution) of the images from the Discovery NM/CT 670 CZT were rated slightly higher than the images from the NaI predicate device.

Additionally, the average overall image quality (IQ, resolution) results for Discovery NM/CT 670 CZT images that were created using the first 75% of the counts of the original image (equivalent to acquiring for 75% of the original time –or- acquiring with a 75% lower injected dose for the original time) were found to be equivalent to the average overall image quality results from the predicate device image produced with 100% of its counts.

Conclusion:

Based on the conformance to standards, development under GE Healthcare's quality system, the successful verification testing, additional engineering testing, and the clinical evaluation, GE Healthcare believes that the Discovery NM/CT 670 CZT is substantially equivalent to the predicate device Discovery NM/CT 670 (K093514), and hence is safe and effective for its intended use.