K093514

DEC 10 2009

510(k) Summary

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

Date:	September, 23, 2009
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/CT 670
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
Predicate Device(s):	K022960- INFINIA; K082816- GE BRIGHTSPEED DELIGHT CT SCANNER SYSTEM; K082506- SYMBIA, VERSION 4.0; K052434- HAWKEYE 4 OPTION FOR DUAL-HEAD VARIABLE ANGLE GAMMA CAMERA
Device Description:	The Discovery NM/CT 670 system is a hybrid SPECT-CT system for performing nuclear cardiology medicine studies, CT studies or SPECT-CT hybrid studies wherein the SPECT and CT studies may be registered and displayed in a fused form on processing and review Workstation. The Discovery NM/CT 670 system is intended to allow healthcare facilities to carry out SPECT and CT studies using the same instrument Major parts of the hybrid system include the following parts : new NM Gantry with Dual detector heads , CT Gantry (same as BrightSpeed Elite (BSD16) gantry), new common patient table , Integrated operation Console including BSD16 operation console and NM operation console & BSD16 Power Distribution Unit .
Intended Use:	The GE Discovery NM/CT 670 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 system, combining Nuclear Medicine (NM) and Computed Tomography (CT) systems, 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 assortment of collimators, 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 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 produce additional images, imaging planes, and analysis results. The system may be used for patients of all ages.

Technology: The Discovery NM/CT 670 employs the same fundamental scientific technology as its predicate devices the Nuclear Medicine SPECT system (NM) K022960- Infinia and the CT system, BrightSpeed Elite K082816- ; The CT part is an identical CT system to its predicate device K082816, 16 slices, (BSD16) except for new equivalent patient table that share common use with the NM system and minor software modifications. The common table meets attenuation requirements for NM and provides equivalent or less attenuation vs. original CT table. The NM part (NM gantry and dual head NM detectors) are improved modification of the NM predicate device K022960- Infinia.

Determination of Substantial Equivalence: The Discovery NM/CT 670 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
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

The Discovery NM/CT 670 did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Discovery NM/CT 670 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

DEC 10 2009

GE Medical Systems Israel, Functional Imaging
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K093514
Trade/Device Name: Discovery NM/CT 670
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS and JAK
Dated: November 11, 2009
Received: November 13, 2009

Dear Mr. Devine:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K093514

Device Name: Discovery NM/CT 670

Indications for Use:

The GE Discovery NM/CT 670 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 system, combining Nuclear Medicine (NM) and Computed Tomography (CT) systems, is intended to produce:

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Prescription Use_X___ AND/OR Over-The-Counter Use_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093514

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