K111445

JUN - 3 2011

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

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

Date:	[April 12, 2011]
Submitter:	GE Healthcare, GE Medical Systems Israel, Functional Imaging 4 HAYOZMA St TIRAT HACARMEL, 30200, ISRAEL
Primary Contact Person:	Tal Bresler-Stramer Regulatory Affairs Leader GE Healthcare, GE Medical Systems Israel, Functional Imaging (972) 4-8563666 (972) 4-8577664
Secondary Contact Person:	John Jaeckle Regulatory Affairs Manager, MI&CT GE Healthcare, 262-424-9547
Device: Trade Name:	Discovery NM 630
Common/Usual Name:	Single Photon Emission Computed Tomography (SPECT)
Classification Names:	21CFR 829.1200 KPS
Product Code:	
Predicate Device(s):	Discovery NM/CT 670 (k093514)
Device Description:	The Discovery NM 630 is an all-purpose dual detector nuclear imaging system intended for 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 main components of the Discovery NM 630 system are: NM Gantry with Dual detector heads, patient table, Remote Control Unit and NM operation console. The Discovery NM 630 is a subsystem of its predicate device Discovery NM/CT 670 (K093514).
Indications for Use:	The GE Discovery NM 630 system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and in assessment of 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 630 system is a Nuclear Medicine (NM) system, which is intended to yield 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.

The GE Discovery NM 630 system may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system may be used for patients of all ages.

Technology: The Discovery NM 630 is a subset of its predicate device the NM/CT hybrid system Discovery NM/CT 670 (k093514). The Discovery NM 630 employs the same fundamental scientific technology as the NM subsystem of its predicate device the NM/CT hybrid system Discovery NM/CT 670 (k093514).

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:

The Discovery NM 630 and its applications are designed to comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. It was developed in accordance with GE's Quality System. 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 630 did not require clinical studies to support substantial equivalence.

Conclusion: The Discovery NM 630 is the stand-alone nuclear medicine functionality/components of its predicate device. It does not introduce and new safety risks, or intended uses. It performs as well or better than similar devices currently on the market and conforms to the recognized standards for NM. GE Healthcare considers the Discovery NM 630 to be as safe, as effective, and is substantially equivalent to the predicate device.

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

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

JUN - 3 2011

Re: K111445
Trade/Device Name: Discovery NM 630
Regulation Number: 21 CFR §892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: May 20, 2011
Received: May 24, 2011

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 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, 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 Form

510(k) Number (if known): K111445

Device Name: Discovery NM 630

Indications for Use:

The GE Discovery NM 630 system is a medical tool intended for use by appropriately trained healthcare professionals to aid in detecting, localizing, diagnosing of diseases and in assessment of 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.
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Prescription Use _____X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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

Mary S Patel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111445