

K121019

APR 19 2012

510(k) Summary

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

Date: March 8, 2012

Submitter: GE Healthcare, GE Medical Systems Israel, Functional Imaging
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Device: Trade Name: Optima NM/CT 640

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): K111445- Discovery NM 630 and K052434- Hawkeye 4 Option
for Dual-Head Variable Angle Gamma Camera

Device Description: The Optima NM/CT 640 system is a combination of the Discovery NM630 gamma camera (K111445), the certified table from the Discovery NM/CT 670 (K093514) and a 4 slice CT subsystem containing previously certified components. It consists of two back-to-back gantries, a single table, a single power distribution unit, a console with single acquisition system and associated accessories (e.g. ECG gating, Table Extender, Head Holder, etc.). The system is delivered with a processing and review workstation (currently Xeleris 3-K093982).

The system is intended to be in clinics or hospitals having normal HVAC controls.

Intended Use: The GE Optima NM/CT 640 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 (NM) system using a variety of scanning modes supported by various acquisition types, and a CT component which is intended specifically for enabling

attenuation correction and anatomical localization on SPECT studies.

Indications for Use:

The GE Optima NM/CT 640 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 Optima NM/CT 640 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 an assortment of collimators, gating by physiological signals, and real-time automatic body contouring.

The GE Optima NM/CT 640 system includes an integrated CT, which is intended specifically for attenuation correction and anatomical localization purposes only, a processing and review workstation, and may include signal analysis and display equipment, patient and equipment supports, components and accessories. The system may be used for patients of all ages.

Utilizing the associated CT portion and post processing, the device can produce attenuation corrected SPECT images using CT-based attenuation maps, as well as functional and anatomical mapping images registered with the SPECT images for purposes of localization and fusion.

The device does not support stand-alone CT operation.

Technology:

The Optima NM/CT 640 utilizes the same fundamental scientific technology as its predicate devices: the Nuclear Medicine system Discovery NM630 (K111445) and the- Hawkeye 4 Option for Dual-Head Variable Angle Gamma Camera (K052434). The NM subsystem of Optima NM/CT 640 is a virtually identical NM

system to its predicate device Discovery NM630, except for the patient table, which is the same table as used on the Discovery NM/CT 670 (093514).

The Optima NM/CT 640 includes an integrated CT subsystem, which is intended specifically for attenuation correction and anatomical localization purposes only. This CT includes a previously certified tube and generator that is software limited to low mA (and hence low dose). The tube itself is the same as used on other GE CT systems such as CT/e, CT/e Dual (K993645, K021491) and Brivo CT 315/325. The CT gantry is capable of much faster rotation speeds than its Hawkeye 4 predicate and includes a new 4 row, optimized for low signal, Data Acquisition System (DAS) and detector. The CT gantry is independent of the NM gantry (however it has integrated covers). The NM- and CT-subsystems share a common patient table.

Determination of Substantial Equivalence:

The Optima NM/CT 640 and its applications are designed and independently tested to comply with recognized voluntary standards and will be certified to 21CFR performance standards as detailed in Section 9, 11 and 17 of this premarket submission. The system was design in accordance with the design controls of GE's quality system. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Module Testing on unit level
- System Integration testing
- Performance testing
- Safety testing

The Optima NM/CT 640 does not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Optima NM/CT 640 to be as safe, as effective, and with performance 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

GE Medical System, Israel, Functional Imaging
% Mr. Ned Devine
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Underwriters Laboratories Inc.
333 Pfingsten Road
NORTBROOK IL 60062

APR 19 2012

Re: K121019
Trade/Device Name: Optima NM/CT 640
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS and JAK
Dated: April 2, 2012
Received: April 4, 2012

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.

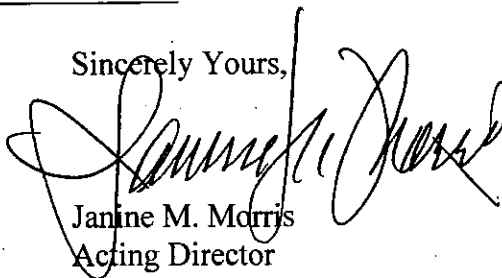
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Janine M. Morris
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 FORM

510(k) Number (if known): K121019

Device Name: **Optima NM/CT 640**

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(Part 21 CFR 801 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
Office of In Vitro Diagnostic Device
Evaluation and Safety

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