K083504

DEC 12 2008

10. 510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Summary Date

September 4, 2008

Device Name

Proprietary Device Name: GE Discovery NM/CT 570c

Establishment Name and Registration Number of Submitter

Name: GE MEDICAL SYSTEMS F.I. HAIFA
Registration Number: 9613299
Corresponding Official: Laurence Bigio; Site QA Manager
GE Medical Systems F.I. Haifa
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Device Classification

Classification Name: System Emission Computed Tomography (per 21CFR 892.1200)
System Computed Tomography (per 21CFR 892.1750)
Common Name: Single Photon Emission Computed Tomography
Computed Tomography X-Ray
Classification Code: 90 KPS & 90 JAK
Panel Identification: Radiology
Classification Class: Class II Product

Type of Submission

Traditional

Reason for 510(k) Submission

Modification of legally marketed devices.

Identification of Legally Marketed Equivalent Devices

Device Name	K Number	Feature
Ventri 1.1	K080124	SPECT system
LightSpeed 7.1	K061817	CT system
Xeleris 2	K051673	Processing and Review Workstation for SPECT, CT and Hybrid SPECT-CT
Infinia LightSpeed	K043381	Hybrid SPECT-CT

Device Description

The GE Discovery NM/CT 570c system is a back-to-back combination of the Ventri 1.1 SPECT scanner (K080124) and the LightSpeed 7.1 CT scanner (K061817), sharing a common LightSpeed 7.1 patient table. In addition to providing CT and SPECT standalone capabilities, it uses the CT images to correct for non-uniform attenuation of the SPECT images and to facilitate localization of the emission activity in the patient anatomy.

Description of Change or Modification

The LightSpeed 7.1 CT System (K061817), the Ventri 1.1 SPECT System (K080124) and the Xeleris 2 Processing and Review Workstation (K051673), had been modified to accommodate for the GE Discovery NM/CT 570c system, by including means to align gantries, share emergency stop circuits, a common table and additional processing software for use of CT for purposes of SPECT attenuation correction.

Intended Use of Device

The intended use of the GE Discovery NM/CT 570c system is primarily to perform combined cardiac SPECT and CT diagnostic imaging applications, including CT-based SPECT attenuation correction and functional-anatomical mapping (registration and fusion).

The GE Discovery NM/CT 570c system intended uses include performing nuclear cardiac imaging procedures for detection and imaging of radioisotope tracer uptake in the patient body for clinical diagnostic purposes as well as performing general Head & Body Computed Tomography (CT) applications

Summary of Studies

Data acquired with uniform phantom shows that SPECT-CT attenuation-corrected images are more uniform than SPECT images without attenuation correction. The images also demonstrate the localization capabilities of the SPECT-CT.

Conclusion

In the opinion of GE MEDICAL SYSTEMS F.I. HAIFA, the GE Discovery NM/CT 570c system is substantially equivalent in terms of safety and effectiveness to the legally marketed Ventri 1.1 (K080124), the legally marketed LightSpeed 7.1 (K061817), the legally marketed Infinia LightSpeed (K061817) and the legally marketed Xeleris 2 Processing and Review Workstation (K051673), based upon similar intended use and system performances.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2008

GE Medical Systems F.I. Haifa
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K083504
Trade/Device Name: GE Discovery NM/CT 570c
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: November 24, 2008
Received: November 26, 2008

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 such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part.807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083504

Device Name: GE Discovery NM/CT 570c

Indications for Use:

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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 Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083504

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(Posted November 13, 2003)