K103489

SECTION 5

SEP - 9 2011

510(k) SUMMARY

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GE Healthcare
GE Medical Systems, LLC

3000 N. Grandview Blvd.
Waukesha, WI 53188

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 Prepared: June 1, 2011

Submitter: GE Healthcare (GE Medical Systems, LLC)
3000 N. Grandview Blvd., W-1140
Waukesha, WI 53188

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DEVICE IDENTIFICATION

Trade Name: GE Veo Reconstruction Option

Common/Usual Name: Veo

Classification Name: Computed Tomography X-ray System per 21CFR892.1750

Product Code: 90-JAK

Predicate Device(s): GE Discovery CT750 HD (K081105)

Manufacturer / Design Location:	GE Medical Systems, LLC (GE Healthcare) 3000 N. Grandview Blvd. Waukesha, WI 53188
Manufacturing Location:	GE Medical Systems, LLC (GE Healthcare) 3000 N. Grandview Blvd. Waukesha, WI 53188
Distributor:	Same as Manufacturer
Marketed Devices:	The GE Veo Reconstruction Option when combined with the GE CT system is of comparable type and substantially equivalent to GE Healthcare's currently marketed Computed Tomography X-ray Systems that comply with the same or equivalent standards and having similar intended use. The GE CT system with the integrated GE Veo Reconstruction Option remains compliant with the same standards as the CT system.

DEVICE DESCRIPTION

The Veo Reconstruction Option is composed of Server hardware and reconstruction software. The Veo reconstruction Server is connected to the CT system's operator console via a dedicated Ethernet connection to receive raw scan data for processing and send back the reconstructed image data when completed. Additionally, some minor changes to the CT system software are made to include functionality for installation and operation of the Veo Reconstruction Option. The option when used with the Discovery CT750 HD system (K081105) is an evolutionary modification and performs as well as or better than the computed tomography devices currently on the market. The product changes are primarily associated with the new reconstruction software and hardware. The Veo Reconstruction Option provides another method for reconstruction to that already provided by the CT system.

The Veo Reconstruction Option is intended for head and whole body CT scans when higher image quality and/or lower dose acquisitions are desired for challenging cases. The GE Veo Reconstruction Option when used with the CT System uses virtually the same materials and identical CT imaging principles as our existing marketed product, Discovery CT750 HD.

INTENDED USE

The Veo Reconstruction Option is intended for head and whole body CT scans when higher image quality and/or lower dose acquisitions are desired for challenging cases.

INDICATIONS FOR USE

The Veo reconstruction option is intended to produce cross-sectional images of the head and body by computer reconstruction of X-ray transmission data taken at different angles and planes, including Axial and Helical (Volumetric) acquisitions for all ages.

When used, it allows for an alternate reconstruction method designed to reduce image noise, increase resolution and improve low contrast detectability in images produced using raw Computed Tomography data from GE CT scanners. The Veo reconstruction option can be used to reduce noise in diagnostic images and also to reduce the dose required for routine imaging, including CT scans of the head, chest, abdomen and pelvis. The Veo reconstruction option may also improve the image quality of low dose non-diagnostic Filtered Backprojection images such that they become diagnostic.

Currently, Veo is for use with the Discovery CT750 HD CT Scanner.

COMPARISON WITH PREDICATE

The GE Veo Reconstruction Option when used with the CT System uses virtually the same materials and identical CT imaging principles as our existing marketed product, Discovery CT750 HD. The Veo Reconstruction Option provides another method for reconstruction to that already provided by the CT system.

The GE Veo Reconstruction Option when combined with the GE CT system is of comparable type and substantially equivalent to GE Healthcare's currently marketed Computed Tomography X-ray Systems. The Veo Reconstruction Option was developed under GE's Quality System and will be initially introduced as an option for the Discovery CT750 HD system (K081105). The GE CT system when using the GE Veo Reconstruction Option remains compliant with the same standards as the CT system.

ADVERSE EFFECTS ON HEALTH

The Veo Reconstruction Option is designed and manufactured under the Quality System Regulations, 21 CFR Part 820. Additionally, risk management is employed through hazard analysis, which identifies potential hazards. These hazards are mitigated through adherence to software development lifecycle procedures aligned with IEC 62304 and through product labeling including user instructions. Functional requirements are demonstrated via testing.

CONCLUSION

The Veo Reconstruction Option when used with a GE CT system is an evolutionary modification and performs as well as or better than the computed tomography devices currently on the market. In addition, when the CT system and the Veo option are combined they remain compliant with the same standards as the CT system alone. The combination of the Veo option and the CT System uses virtually the same materials and identical CT imaging principles as our existing marketed product, Discovery CT750 HD (K081105).

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

Mr. Andrew Menden
Regulatory Affairs Leaser, MI&CT
GE Healthcare
GE Medical Systems, LLC
3000 N. Grandview Blvd.
WAUKESHA WI 53188

SEP - 9 2011

Re: K103489
Trade/Device Name: GE Veo Reconstruction Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 1, 2011
Received: June 2, 2011

Dear Mr. Menden:

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

510(k) Number (if known): K103489

Device Name: GE Veo Reconstruction Option

Indications for Use:

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Currently, Veo is for use with the Discovery CT750 HD CT Scanner.

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 IF 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

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