K123596

FEB 8 2013

GE Medical Systems, LLC
510(k) Premarket Notification Submission for: Optima CT520

510(k) Summary

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

Date:	November 20th, 2012
Submitter:	GE Healthcare (GE Hangwei Medical System Co.,Ltd) No.2 North Yongchang Road Beijing Economic & Technological Development Area Beijing, China 100176
Primary Contact Person:	Helen Peng Regulatory Affairs Leader GE Healthcare Phone Number: (262)-424-8222 FAX Number: (262) 364-2506
Secondary Contact Person:	John Jaeckle Chief Regulatory Strategist GE Healthcare Phone Number: 262-424-9547
PRODUCT IDENTIFICATION	Optima CT520
Device Trade Name:	Computed Tomography X-ray System
Common/Usual Name:	
Classification Names:	Computed Tomography X-ray System 21CFR892.1750
Product Code:	JAK
Predicated Device(s):	GE BrightSpeed Elite Select (K082816)

Marketed Devices:

The Optima CT520 is of comparable type and substantially equivalent to GE Healthcare's currently marketed Computed Tomography X-ray Systems that comply with the same standards. In addition, the system has similar intended use as other GE Computed Tomography X-ray Systems and the same intended use and indications for use as the unmodified device. The system completed all design controls activities including risk management, verification and validation testing per GE's quality management system.

Device Description:

The Optima CT520 CT Scanner System is composed of a gantry, patient table, operator console, and line voltage adaptor. It also includes image acquisition hardware, image acquisition and reconstruction software, associated accessories and connections/interfaces to accessories.

The system generates images through the computer reconstruction of data acquired at different angles and planes of the rotating gantry. The gantry can rotate at up to 0.8 seconds per rotation, and can acquire up to 16 slices/rows of data per rotation with a maximum total collimation coverage of 20mm in the z direction. The system can be operated in Axial, Cine, Helical, Cardiac and Gated acquisition modes.

To improve the siting footprint, the power distribution unit (PDU) has been integrated into the gantry base; except for standalone line voltage adaptor, if needed. The PDU components' function and performance remain the same. This change has been fully tested and certified by a NRTL to continue to meet all applicable IEC/UL safety standards.

The Optima CT520 represents evolutionary modifications to the predicate device (BrightSpeed Elite Select CT System (K082816)). The modifications include hardware upgrades due to technology obsolesces (e.g. console), ROHS compliance, system siting footprint optimization, and IEC Edition 3 compliance, as well as software changes to improve workflow and usability, incorporate Dose Check and quality fixes, assist in product marketing position by feature availability, and feature technology flow-down from cleared premium tier products (e.g. ASiR). The Optima CT520 is a general purpose, mid-tier 16-slice CT scanner that incorporates GE's innovative technology and feature functionality.

The Optima CT520 uses virtually the same materials and identical operating principle as our existing marketed product, except in the case of using the compensatory ROHS compliance material. The image chain components (tube, collimator, detector, DAS) are virtually identical to the BrightSpeed Elite Select.

The changes do not affect the intended use, the indications for use, patient population nor fundamental operating principles of the currently commercially available predicate system and are the identical or similar to other GE CT systems and features previously cleared.

Intended Use:

The Optima CT520 system is intended for head, whole body, cardiac and vascular X-ray Computed Tomography applications

Indication for Use:

The GE Optima CT520 Computed Tomography X-ray system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, patient for all ages, including Axial, Cine, Helical, Cardiac, and Gated acquisitions. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient, and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The GE Optima CT520 CT Scanner System is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Technology:

The Optima CT520 employs the same fundamental scientific technology as its predicate device and other cleared GE CT systems an features.

Adverse Effects on Health:

Potential electrical, mechanical, and radiation hazards are identified in risk management including hazard analysis and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (UL/CSA and IEC60601-1 Ed.3 and associated collateral and particular standards for CT).
- Compliance to applicable CDRH 21CFR subchapter J requirements.
- Compliance to NEMA XR-25

The device is designed and manufactured under the Quality System Regulations of 21 CFR 820.

Determination of Substantial Equivalence:

The Optima CT520 is a modified device based on the hardware and software platform of the predicate device. It was designed and is manufactured under GE's quality system that meets the Quality System Regulations of 21CFR 820 and ISO 13485. All the changes were fully verified and validated to the acceptance criteria per GE Healthcare's design control procedures under our quality system before the modified device was commercially introduced in applicable countries. In addition the Optima CT520 has been successfully tested to demonstrate compliance with IEC 60601-1 (edition 3) and its associated collateral and particular standards, 21CFR Subchapter J, and NEMR XR-25. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Testing on unit level (Module Verification)
- Integration testing (System Verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Clinical data was not needed to establish safety and effectiveness, all changes were able to be fully verified and validated on the bench, and the testing did not reveal any new questions of safety or effectiveness. GE believes the Optima CT520 is of comparable type and substantially equivalent to our currently marketed system: BrightSpeed Elite Select (K082816).

Summary of Additional Testing

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering testing was performed to provide the requisite data to substantiate performance claims, safety and efficacy, and ultimately substantial equivalence. Even though clinical data was not needed to establish safety and effectiveness, sample clinical images were provided.

Engineering Testing

The additional engineering testing performed was:

- Testing to substantiate the updated product claims.
- Acceptance testing performed in accordance with IEC 61223-3-5
- Simulated large patient imaging testing.

Sample Clinical Images

Sample clinical images representing a various acquisition modes and body regions were provided for reference. Along with the images an assessment of diagnostic quality using a Likert scale provided by two independent radiologists.

Conclusion

Based on the conformance to standards, development under our quality system, the engineering testing , and sample clinical images provided, GE Healthcare believes that the Optima CT520 is as safe and effective, and performs in a substantially equivalent manner to the predicate device, BrightSpeed Elite Select (K082816).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 8, 2013

Helen Peng
Regulatory Affairs Leader
GE Medical System
3000 N. Grandview Blvd
WAUKESHA WI 53188

Re: K123596
Trade/Device Name: Optima CT520
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 20, 2012
Received: November 21, 2012

Dear Ms. Peng:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123596

Device Name: Optima CT520

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This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results. The GE Optima CT520 CT Scanner System is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications. The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123596