



GE Healthcare / GE Medical Systems. LLC

JUL 20 2011

510(k) Premarket Notification Submission

Product Name: Optima CT660

### **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:** May 3, 2011

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

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Regulatory Affairs Leader MI & CT  
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#### **Product Identification**

**Device Trade Name:** Optima CT660

**Common/Usual Name:** Computed Tomography X-ray System

**Classification Name:** Computed Tomography X-ray System per 21CFR 892.1750

**Product Code:** 90-JAK

**Manufacturer:** GE Healthcare Japan Corporation  
**/Design Location:** 7-127 Asahigaoka, 4-chome, Hino-shi  
Tokyo, 191-8503, Japan



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**Manufacturing Location(s):** GE Healthcare Japan Corporation  
7-127 Asahigaoka, 4-chome, Hino-shi  
Tokyo, 191-8503, Japan

GE Medical Systems, LLC  
3000 N. Grandview Blvd.  
Waukesha, WI 53188

**Distributor:** GE Medical Systems, LLC  
3000 N. Grandview Blvd.  
Waukesha, WI 53188

**Marketed Devices:**

The Optima CT660 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 indications for use as other GE Computed Tomography X-ray Systems and identical indications as the unmodified device. The system is labeled as the Optima CT660 however the commercial names used for the configurations are Optima CT660 or Optima CT660 s.

**Predicate Device:**

K082761 - LightSpeed VCT (GE LightSpeed 7.2 CT Scanner System)

**Device Description:**

The Optima CT660 and its associated configurations/packages is a multi-slice CT scanner system consisting of a gantry, patient table, operator console, power distribution unit (PDU), associated accessories, and connections/interfaces to accessories. The system includes image acquisition hardware, image acquisition & reconstruction software, associated accessories, and connections/interfaces to accessories. ASiR advanced reconstruction technology is also an option on this product and was cleared in K093581.

The Optima CT660 CT system is intended to be a head and whole body CT system incorporating the same basic fundamental operating principles and the same indications for use as the predicate device. Materials and construction are equivalent to our existing marketed products which are compliant with UL 60601-1, IEC 60601-1 and associated collateral and particular standards, and 21 CFR Subchapter J. It has been developed under the same GE quality system and has completed all design controls, including risk management, verification and validation.



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**Indications for Use:**

The Optima CT660 is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), 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 system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

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 CT660 employs the same fundamental scientific technology as its predicate device.

**Adverse Effects on Health:**

Potential electrical, mechanical and radiation hazards are identified in a 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 IEC).
- Compliance to applicable CDRH 21CFR subchapter J requirements.

The device is designed and manufactured under the Quality System Regulations of 21CFR820.



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**Determination of Substantial Equivalence:**

The Optima CT660 has completed testing and is in compliance IEC 60601-1 and associated collateral and particular standards, and 21 CFR Subchapter J. The device has completed all testing per our quality system as well as comparison testing to the unmodified device. It was designed and is manufactured under the Quality System Regulations of 21 CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

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

**Conclusion:**

The Optima CT660 does not raise in any new potential safety risks and performs as well as devices currently on the market. The Optima CT660 CT system has been certified in accordance with the same standards as the predicate device. GE Healthcare considers the Optima CT660 to be as safe, as effective, and performance 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

Ms. Tracey Ortiz  
Regulatory Affairs Lead Engineer-MI & CT  
GE Healthcare, GE Medical Systems, LLC  
3000 N. Grandview Blvd. W-1140  
WAUKESHA WI 53188

JUL 20 2011

Re: K110227  
Trade/Device Name: Optima CT660  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: May 3, 2011  
Received: May 5, 2011

Dear Ms. Ortiz:

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.

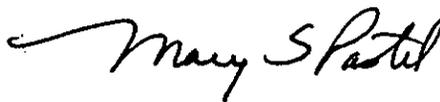
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



GE Healthcare / GE Medical Systems, LLC  
510(k) Premarket Notification Submission  
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Indications for Use

510(k) Number (if known): K110227

Device Name: Optima CT660

Indications for Use:

The Optima CT660 is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), 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.

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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   
(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)

Mary Spatel

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

610K

K110227