K132410
Page 1 of 6

JAN 17 2014

510(k) Summary

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

Date:	August 1st, 2013
Submitter:	GE Healthcare GE Healthcare (GE Medical Systems, LLC) 3000 N. Grandview Blvd., W-1140 Waukesha, WI 53188
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Secondary Contact Person:	John Jaeckle Chief Regulatory Affairs Strategist GE Healthcare (GE Medical Systems, LLC) Tel: 262-424-9547 Fax: 262-364-2506 e-mail: John.Jaeckle@med.ge.com Helen Peng Regulatory Affairs Manager, MI&CT GE Healthcare (GE Medical Systems, LLC) Tel: 262-548-5091 Fax: 262-364-2506 e-mail: hong.peng@med.ge.com
Product Identification:	Discovery CT590 RT/Optima CT580
Device Trade Name:	Discovery CT590 RT/Optima CT580
Common/Usual Name:	Discovery CT590 RT Optima CT580 Optima CT580 W Optima CT580 RT
Classification Names:	Computed Tomography X-ray System 21CFR892.1750
Product Code:	JAK

Predicated Device(s):	GE Discovery CT 590RT/ Optima CT580 (K093581) GE Advantage 4D(K032915)
Manufacturer(s):	GE Hangwei Medical Systems Co., Ltd No. 1 North Yong Chang North Street Beijing Economy & Technology Development Zone Beijing, 100176, China
	GE Medical Systems, LLC (GE Healthcare) 3000 N. Grandview Blvd. Waukesha, WI 53188

Marketed Devices:

The Discovery CT590 RT and Optima CT580 with Deviceless 4D option is of comparable type and substantially equivalent to GE Healthcare's currently marketed Computed Tomography X-ray Systems Discovery CT590 RT/ Optima CT580 (K093581) and 4D post-processing device Advantage 4D (K032915). The commercial names currently used in the US market are any of the following configuration names: Discovery CT590 RT and Optima CT580, Optima CT580 RT, or Optima CT580 W and will remain unchanged.

Device Description:

Deviceless 4D Option (D4D)

Deviceless 4D is a software option used for capturing the respiratory cycle and binning the image such that the target motion may be obtained for treatment planning. Deviceless 4D has the same intended use and clinical output of Advantage 4D (A4D,K032915) which was included in the cleared Discovery CT590 RT/ Optima CT580 (K093581) CT system. Deviceless 4D is an alternative and efficient solution for 4D imaging and virtual simulation without the need for an external respiratory monitoring device.

Deviceless 4D first uses a "scout-like" scan type called "SmartBreath" to determine the stable breathing cycle period that is then automatically implemented into the scan parameters for the Cine scans.

D4D incorporates a design that uses internal anatomic features of the respiratory cycle obtained during the Cine scans for image binning. These features are temporally registered to the actual breathing cycle.

Discovery CT590 RT and Optima CT580 series:

The Discovery CT590 RT and Optima CT580 series of systems are composed of a gantry, patient table, operator console, computer, and power distribution unit (PDU), and interconnecting cables. The systems include image acquisition hardware, image acquisition, reconstruction software, associated accessories, and connections/interfaces to accessories.

The current systems are an evolutionary modification to the Discovery CT590 RT and Optima CT580 (K093581) by adding software features, quality fixes, IEC Ed. 3 compliance, and modifications in hardware for RoHS compliance and technology obsolesces.

The "16-slice", system generates cross-sectional images of the body by computer reconstruction transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric) and gated acquisition modes. It has a maximum total collimation coverage of 20mm in the z direction.

The Discovery CT 590 RT and Optima CT 580 series of systems are designed to be a head and whole body CT systems incorporating the same basic fundamental operating principles and similar indications for use. Materials and construction are equivalent to our existing marketed products, which are compliant with UL60601 -1, IEC 60601-1 and associated collateral and particular standards, NEMA XR-25, and 21CFR Subchapter J. The accompanying documents also contain the information in support of IEC61223-3-5 and IEC61223-2-6 for acceptance and constancy testing.

The system was developed under design controls process including risk management, software life cycle management, and design output testing per GE's quality management system.

Intended Use:

The system is intended to be used for head and whole body computed tomography.

Indication for Use:

The Discovery CT590 RT/Optima CT580 Computed Tomography Systems are 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), and Gated (Respiratory and Cardiac) acquisitions for all ages. 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 Discovery CT590 RT/Optima CT580 Computed Tomography Systems are indicated for head, whole body, 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.

The system is capable of assisting with minimally invasive procedures such as biopsy and ablation of tumors and pathology. The system allows imaging of Bariatrics patients, up to and including the morbidly obese population (BMI > 40).

The system can acquire CT anatomical images that are clinically useful in the simulation and planning of radiation therapy for the treatment of cancer.

If the Devicelss 4D option is included on the system, the system can be used to efficiently provide and display CT images of all phases of a breathing cycle for the evaluation of respiration-induced motion of the chest for use with therapy planning and simulation.

The software calculates the breathing period to determine the Cine acquisition duration and the cine time between images which is automatically imported to the 4D cine acquisition. The software then uses information derived from the imaging for the binning process.

Technology:

The Discovery CT Discovery CT590 RT/Optima CT580 with Deviceless 4D options employs the same fundamental scientific technology as that of its predicate devices and other image processing applications. The only modification for this submission is for the Deviceless 4D feature which is described above in the "Device Description" section of the summary. The Discovery CT590 RT / Optima CT580 with Deviceless 4D option is built on the cleared Discovery CT590 RT / Optima CT580 (K093581) hardware and software platform. The vast majority the software features and functions are common between the two products. The D4D option has the same intended use as its predicated device Advantage 4D (K032915) and employs the same fundamental process of using data from transient motions of the chest to sort the Cine images into phases to reduce the effects of respiratory motion.

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 CFR820.

Determination of Substantial Equivalence:

The Discovery CT590 RT and Optima CT580 including the Deviceless 4D option was developed under GE's quality system and design controls. Testing for functionality and product claims were performed to ensure that functional requirements have been met, and that core functions execute as expected. Safety and Effectiveness has been established through bench testing which included image comparisons between A4D and D4D, as well as adherence to design controls and conformance to standards.

External clinical evaluation was not needed to establish safety and effectiveness, all changes were able to be fully evaluated on the bench, and the testing did not reveal any new questions of safety or effectiveness. GE believes the totality of all of the combined changes is considered substantially equivalent to the unmodified device cleared in K093581 and K032915.

The substantial equivalence was also based on software documentation for a "moderate" level of concern device.

Summary of Additional Testing

System and Subsystem Verification have been successfully executed under GE's quality system, which demonstrated the Discovery CT590 RT/Optima CT580 met design requirements. Engineering testing also included testing to substantiate the updated product claims and acceptance testing performed in accordance with IEC 61223-3-5. Bench testing of and image review of the D4D feature provided additional data that this feature works both as intended and to provide the requisite data to substantiate performance claims, safety and efficacy, and ultimately substantial equivalence.

The testing performed included testing using a commercially available breathing phantom with anatomical features to demonstrate the equivalence of the SmartBreath technique in capturing the breathing periodicity as compared to that of a respiratory gating device. Additionally clinical datasets from GE's internal development data base were used to compare the binning and measurement of D4D to the predicate feature

A4D and demonstrate substantial equivalence. Statistical analysis tools such as the Scatter plot, the Bland-Altman plot and correlation analysis were used to analyze the bench test data which showed the D4D feature performs equivalently to its predicate device Advantage 4D.

Conclusion

The proposed Discovery CT590 RT/Optima CT580 with Deviceless 4D Option is an evolutionary modification to the cleared Discovery CT590 RT and Optima CT580 CT systems (K093581). It does not result in any new potential safety risks and performs as well as devices currently on the market. The Discovery CT590 RT and Optima CT580 series of systems complies the same or updated standards as well as 21CFR 1020.30 and 1020.33 regulation. GE Healthcare believes the Discovery CT590 RT and Optima CT580 with Deviceless 4D series of CT systems is as safe and effective, and performs in a substantially equivalent manner to the predicate devices, Discovery CT590 RT / Optima CT580 (K093581) and Advantage 4D (K032915).

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

January 17, 2014

GE Medical Systems, LLC dba GE Healthcare
% Ms. Helen Peng
Regulatory Affairs Manager, MI&CT
3000 N Grandview Blvd.
WAUKESHA WI 53188

Re: K132410
Device Name: Discovery CT590 RT/Optima CT580 CT System with Deviceless 4D Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: December 16, 2013
Received: December 17, 2013

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.

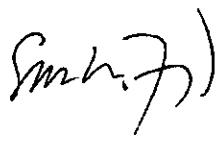
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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. 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/MedicalDevices/ResourcesforYou/Industry/default.htm..

Sincerely yours,



for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132410

Device Name
Discovery CT590 RT/Optima CT580

Indications for Use *(Describe)*
The Discovery CT590 RT/Optima CT580 Computed Tomography Systems are 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), and Gated (Respiratory and Cardiac) acquisitions for all ages. 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.

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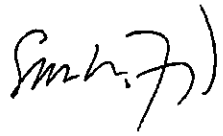
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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