DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 16, 2016

GE Medical Systems, L.L.C.
% Ms. Helen Peng
Regulatory Affairs Manager
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K163213
Trade/Device Name: Revolution CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 15, 2016
Received: November 16, 2016

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 Industry and Consumer Education 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 Industry and Consumer Education 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

Robert Ochs, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163213

Device Name
Revolution CT

Indications for Use *(Describe)*

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver, kidney, pancreas, etc. The system may acquire data using Axial, Cine, Helical, Cardiac, and Gated CT scan techniques from patients of 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 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.

If the spectral imaging option is included on the system, the system can acquire CT images using different kV levels of the same anatomical region of a patient in a single rotation from a single source. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. This approach enables images to be generated at energies selected from the available spectrum to visualize and analyze information about anatomical and pathological structures.

GSI provides information of the chemical composition of renal calculi by calculation and graphical display of the spectrum of effective atomic number. GSI Kidney stone characterization provides additional information to aid in the characterization of uric acid versus non-uric acid stones. It is intended to be used as an adjunct to current standard methods for evaluating stone etiology and composition.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: November 15th, 2016

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

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PRODUCT IDENTIFICATION

Device Trade Name: Revolution CT

Regulation Name: Computed Tomography X-ray System
Regulation: 21CFR 892.1750
Classification : Class II
Product Code: JAK
Manufacturer / Design Location:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Manufacturing Location(s):
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Marketed Devices:

Revolution CT with GSI option is a CT device with modifications made to the predicate device Revolution CT (K133705) to enable Gemstone Spectral Imaging (GSI) option. It is of comparable type and substantially equivalent to its predicate device and GE's other currently marketed Computed Tomography X-ray Systems that comply with the same standards. This 510(k) submission for the Revolution CT system includes the same intended use and substantially equivalent indications for use as its predicate device, the GE Revolution CT (K133705) and reference device GE Discovery CT750 HD (K120833). The existing indications for use of Revolution CT are expanded to include the GSI capability, which is verbatim copy from that of the reference device Discovery CT 750HD. The system is labeled as the Revolution CT.

Predicate Device:

Device Name:	Revolution CT
510(k) number:	K133705 cleared 4/11/2014
Manufacturer:	GE Medical Systems, LLC (same as that of proposed device)
Regulation Name:	Computed Tomography X-ray System
Regulation:	21CFR 892.1750
Classification:	Class II
Product Code:	JAK

Reference Device:

Device Name:	Discovery CT750 HD
510(K) number:	K081105 cleared 5/9/2008, K120833 cleared 6/12/2012
Manufacturer:	GE Medical Systems, LLC (same as that of proposed device)
Regulation Name:	Computed Tomography X-ray System
Regulation:	21CFR 892.1750
Classification:	Class II
Product Code:	JAK

Device Description: Revolution CT with GSI Option

The Revolution CT is a multi-slice (256 detector row) CT scanner consisting of a gantry, patient table, scanner desktop (operator console), system cabinet, power distribution unit (PDU), and interconnecting cables. The system includes image acquisition hardware, image acquisition and reconstruction software, and associated accessories.

GE has modified the cleared Revolution CT (K133705) within our design controls to include the Gemstone™ Spectral Imaging (GSI) Option. GSI is the state-of-the-art single source, projection-based, spectral CT application. It is GE's unique dual energy design and implementation which offers clear advantage over traditional dual source Dual Energy implementation. This feature has been previously cleared on Discovery CT750 HD (K081105, K120833) and it is fundamentally the same technology on Revolution CT. Revolution CT however offers a few technology improvements to enable Volume GSI with up to 80mm GSI z-collimation, 245mm/s GSI volumetric scan speed, dose neutrality and more improved workflow to support GSI in routine scanning.

The GSI Option on Revolution CT is also commercially referenced as GSI Xtream or Volumetric GSI.

The Revolution CT with GSI is designed to be a head and whole body powerful Volume High Definition CT scanner that is designed to provide best-in-class technologies for whole organ coverage, high image quality and responsible dose performance. Revolution CT with GSI option incorporates the same basic fundamental operating principles as the existing marketed products Revolution CT and Discovery CT750 HD.

Intended Use

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

Indications for Use:

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver, kidney, pancreas, etc. The system may acquire data using Axial, Cine, Helical, Cardiac, and Gated CT scan techniques from patients of 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.

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Technology of GSI Feature:

Gemstone Spectral Imaging is GE's unique implementation of the dual energy scan modes that utilizes fast kVp switching x-ray source (switching between two different energy levels of X-rays from view to view during a single rotation) and ultra-fast response Gemstone detector to acquire almost perfectly registered dual energy CT data. The data is then processed through projection domain material decomposition algorithms to generate material density maps (MD), monochromatic images (MC) and virtual unenhanced images (VUE). This data can be utilized to identify material specific differences in attenuation in terms of Water, Iodine, Calcium, Uric Acid, Fat and Hydroxyapatite (HAP) basis-pair images, allowing monochromatic and material representations. Metal Artifact Reduction (MAR) algorithms can also be applied to all GSI images to reduce artifacts due to the presence of metal.

GSI can provide:

- excellent temporal and spatial registration to avoid mis-registration artifacts due to motion in dual energy CT
- Advanced material differentiation, classification and quantification
- Optimization of contrast-to-noise ratio (CNR)
- Reduction in artifacts due to beam hardening and metal.

Determination of Substantial Equivalence:

The main change in the proposed device for this submission is the addition of the GSI capability. The table below summarizes the substantive feature/technological differences between the predicate device, the reference device and the proposed device:

Features	**Discovery CT750 HD (Reference Device, K081105, K128033)**	**Revolution CT (Predicate Device, K133705)**	**Revolution CT with GSI Option (Proposed Device)**

Features	**Discovery CT750 HD (Reference Device, K081105, K128033)**	**Revolution CT (Predicate Device, K133705)**	**Revolution CT with GSI Option (Proposed Device)**
Scan Modes	Scout Axial Helical Cine Cardiac Gated High Definition Interventional (Step+Shoot) Interventional(SmartView) GSI GSI Cardiac	Scout Axial Helical Cine Cardiac Gated High Definition	Scout Axial Helical Cine Cardiac Gated High Definition Interventional(Step+Shoot) GSI
GSI	Axial up to 40 mm Helical up to 40 mm Cardiac up to 40mm High Res	No	Axial up to 40 mm Helical up to 80mm
GSI MAR (Metal Artifact Reduction)	Yes	No	Yes
GSI VUE (Virtual UnEhnahced)	Yes	No	Yes
SmartStep	Yes	No	Yes
High Pitch Helical (hyper Drive)	No	No	Yes

The Revolution CT with GSI option has completed testing and is in compliance with IEC 60601-1 Ed. 3 and its associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25, XR-26, XR-28 and XR-29. The proposed device has successfully completed all testing per our quality system as well as comparison testing to the predicate device. It was designed and is manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. 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)

GE believes the Revolution CT system is of comparable type and substantially equivalent to our currently marketed system Revolution CT (K133705) and Discovery CT750 HD (K120833).

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

Summary of Additional Testing

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering (non-Clinical testing) and clinical performance testing was performed to provide the requisite data to substantiate performance claims, the revised indications, and ultimately substantial equivalence.

Non-Clinical Testing

The performance evaluation testing used a variety of phantoms representing head and body, and clinical datasets to provide technical substantiation of the Gemstone Spectral Imaging (GSI) performance on the Revolution CT. Various mathematical and statistical analyses were performed to demonstrate that each performance item was successfully verified and substantiated for data acquisition and optimized image generation.

Clinical Testing

Sample clinical data was collected from 51 subjects at two sites (one in the US and one in Canada) with the approval of appropriate ethics committee and in accordance with applicable US and Health Canada regulations as well as GE Healthcare's quality system's procedures for such evaluations.

The intent of the study was to obtain a sample set of clinical images across different patient populations, clinical scenarios, and scanning protocols/techniques and to evaluate these images for image quality related to diagnostic use, reduction of metal artifacts using the MAR algorithm, and suppression of iodine in contrast enhanced acquisitions using VUE algorithm. Patients were selected for potential recruitment to meet these needs. Any patient who met these criteria stated in the Protocol and who voluntarily signed the Informed Consent Form was recruited.

This sample image data was representative of a wide range of anatomical coverage and patient indications, and was representative of how the Revolution CT with GSI may be used in a clinical environment. The images were evaluated by 6 board certified and qualified radiologists at different institutions in the United States of America for clinical acceptance and image quality using a 5 point Likert scale. Each data set was read by three different radiologists depending on their area of expertise.

The results of this clinical assessment demonstrate the acceptable diagnostic imaging performance of the GE Healthcare Revolution CT with GSI option.

Substantial Equivalence Conclusion:

Based on the conformance to standards, development under our quality system, and the engineering and clinical testing provided, GE Medical Systems believes that the Revolution CT with GSI option is as safe and effective, and performs in a substantially equivalent manner to the predicate device Revolution CT (K133705).