GE Medical Systems, LLC
Laura Turner
Regulatory Affairs Leader
3000 N. Grandview Blvd,
WAUKESHA, WI 53188

July 26, 2019

Re: K191777
Trade/Device Name: Revolution CT, Revolution CT ES, Revolution Apex, Revolution CT with Apex edition
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: July 1, 2019
Received: July 2, 2019

Dear Laura Turner:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191777

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 nonuric 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY OF SAFETY AND EFFECTIVNESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h):

Date: July 1, 2019

Submitter:
GE Medical Systems, LLC
3000 North Grandview Blvd
Waukesha, WI 53188

Primary Contact:
Laura Turner
Regulatory Affairs Leader
GE Healthcare
Phone 262-548-4588
Email: laura.turner@ge.com

Secondary Contacts:
Helen Peng
Regulatory Affairs Director
GE Healthcare
Tel: 262-424-8222
Email: hong.peng@med.ge.com

John Jaeckle
Chief Regulatory Affairs Strategist
GE Healthcare
Tel: 262-424-9547
Email: john.jaeckle@med.ge.com

PRODUCT IDENTIFICTION

Device Name: Revolution CT, Revolution CT ES, Revolution CT with Apex edition, Revolution Apex

Regulation number/ Product Code 21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Classification Class II

Predicate Device Information:

Device Name	Revolution CT
Manufacturer	GE Medical System, LLC. 3000 North Grandview Blvd Waukesha, WI 53188
510(k) number	K163213 cleared on December 16, 2016
Regulation number /product Code	21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description: Revolution CT Family with SmartScout

The Revolution CT family of products including Revolution CT, Revolution CT ES and Revolution Apex are multi-slice 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. The Revolution CT ES has 128 detector rows with 80mm coverage while the Revolution CT and Revolution Apex have 256 detector rows with 160mm detector coverage.

GE has modified the cleared Revolution CT (K163213) within our design controls to include the SmartScout Option to offer optimized thermal management and improved workflow. The SmartScout mode, if selected by the user, allows for performance of tube warmups during patient scout scanning, eliminating user intervention and wait times for tube warmup. It guides the user to the optimal scout scanning parameters, in order to optimize image quality and dose during patient scanning. The user will still have access to the Regular Scout mode where all traditional routine scout technique settings can be accessed and manually prescribed, such as kV, mA, and cradle speed. SmartScout is an added capability and does not remove access to Regular scout mode.

Qualitative and quantitative phantom studies demonstrate that the SmartScout delivers the similar CT Scout image quality at the similar size-appropriate dose levels (CTDIvol) compared to regular Scout scan.

The SmartScout option will be offered on the Revolution Apex system configuration initially and can be ported to Revolution CT and Revolution CT ES in the future.

This modified system has the same intended use and indications for use as its predicate device. The modified system employs the same basic fundamental operating principles as the existing marketed product Revolution CT, and is of comparable type and substantially equivalent to its predicate device.

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.

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.

Technology of SmartScout

The SmartScout feature involves hardware and software changes.

The change to implement SmartScout involves minor changes to the source collimator, and corresponding software modifications to manage the new scout scan mode as well as managing the tube thermal conditions, while also meeting a user-selected patient CTDIvol for the scout. SmartScout accomplishes this dual concurrent goal in addition to delivering equivalent performance to Regular scout in terms of sizing of the patient anatomy for the purposes of AEC and diagnostic scan range prescription.

The workflow for SmartScout is designed to be as similar as possible to that of the Regular scout mode. The need for a tube warmup is dependent upon on the system-specific patient throughput and prior scanning history.

The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

Specification/ Attribute	**Predicate Device** **Revolution CT (K163213)**	**Proposed Device**
Patient Population	The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications for patients of all ages	Same
Contraindications	None	Same
Source Collimator	Wolverine Collimator • 160 mm Aperture • 5 beam locations (small, medium, large, Calibration Filter (air), blocked)	Wolverine 2 Collimator • 160 mm Aperture • **6 beam locations** (small, medium, large, **large + copper**, Calibration Filter (air), blocked)
Scan Mode	Scout Axial Helical Cine Cardiac Gated High Definition Fluoro (axial) GSI	Scout Axial Helical Cine Cardiac Gated High Definition Fluoro (axial) GSI **SmartScout**

Determination of Substantial Equivalence

The Revolution CT Family with SmartScout 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 Family system is of comparable type and substantially equivalent to our currently marketed system Revolution CT (K163213).

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) 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 to provide technical substantiation of the SmartScout performance on the Revolution Apex. 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. The evaluation also included pediatric phantom evaluation.

Clinical Testing

The Revolution CT family with SmartScout can be fully tested on the engineering bench thus no additional clinical testing was required.

Substantial Equivalence Conclusion:

Based on the conformance to standards, development under our quality system, and the engineering testing provided, GE Medical Systems believes that the Revolution CT with SmartScout option is as safe and effective, and performs in a substantially equivalent manner to the predicate device Revolution CT (K163213).