GE Medical Systems, LLC
% Ms. Katelyn Rowley
Regulatory Affairs Leader
3000 N Grandview Blvd.
WAUKESHA WI 53188

December 17, 2021

Re: K213715
Trade/Device Name: Revolution CT, Revolution CT ES, Revolution CT with Apex edition, Revolution CT ES with Apex edition, Revolution Apex, Revolution Apex Elite, Revolution Apex Plus, Revolution Apex Select, Revolution CT Power, and Revolution Apex Pro
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: November 23, 2021
Received: November 24, 2021

Dear Ms. Rowley:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213715

Device Name
Revolution CT, Revolution CT ES, Revolution CT with Apex edition, Revolution CT ES with Apex edition, Revolution Apex, Revolution Apex Elite, Revolution Apex Plus, Revolution Apex Select, Revolution CT Power, Revolution Apex Pro

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 systems with 160 mm detector coverage have 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.

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K213715

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: November 23, 2021

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

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PRODUCT IDENTIFICTION

Device Name: Revolution CT, Revolution CT ES, Revolution CT with Apex edition, Revolution CT ES with Apex edition, Revolution Apex , Revolution Apex Elite, Revolution Apex Plus, Revolution Apex Select, Revolution CT Power, Revolution Apex Pro

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, Revolution CT ES, Revolution Apex, Revolution CT with Apex Edition
Manufacturer	GE Medical System, LLC. 3000 North Grandview Blvd Waukesha, WI 53188
510(k) number	K191777 cleared on July 26, 2019
Regulation number /product Code	21 CFR 892.1750 Computed tomography x-ray system / JAK

Reference Device Information:

Device Name	SnapShot Freeze 2
Manufacturer	GE Medical System, LLC. 3000 North Grandview Blvd Waukesha, WI 53188
510(k) number	K183161 cleared on February 13, 2019
Regulation number /product Code	21 CFR 892.1750 Computed tomography x-ray system / JAK;LLZ

Device Description: Revolution CT Family with 0.23 s/rotation

The Revolution CT family of products, including Revolution CT, Revolution CT ES, Revolution CT with Apex edition, Revolution CT ES with Apex edition, Revolution Apex, Revolution Apex Elite, Revolution Apex Plus, and Revolution Apex Select, Revolution CT Power, Revolution Apex Pro are multi-slice CT scanners 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 (K191777) within our design controls to include the 0.23 s/rot option. The 0.23s/rot option can be used with axial scan acquisitions and is especially beneficial during certain cardiac scan acquisitions. The scan workflow and user interface remain

identical to the of the predicate device, with the exception that the user now has the option to select 0.23 s/rot in addition to other gantry rotation speeds.

The addition of a new maximum gantry rotation speed leads to updates to system performance claims about maximum temporal resolution when combined with the optional Snapshot Freeze 2 (K183161) feature.

This modified system has the same intended 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 systems with 160 mm detector coverage have 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.

Technology of Revolution Apex with 0.23 s/rot Option

The 0.23 s/rot option involves hardware and software changes.

The new 0.23 s/rot capability requires modifications to the current power pan, detector thermal system, and certain configurations require modifications to system covers. The 0.23 s/rot feature does not eliminate any existing functionality: a software option key is provided which, when activated, enables the user to select a rotation speed of 0.23 s/rot for certain acquisitions. The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device with differences underlined:

Specification/ Attribute	**Predicate Device** **Revolution CT (K191777)**	**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
Gantry	➢ 80 cm patient bore ➢ Rotation Speeds: 0.28, 0.35, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, and 1.0 seconds per rotation.	➢ 80 cm patient bore ➢ Rotation Speeds: 0.23, 0.28, 0.35, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, and 1.0 seconds per rotation.
Power Distribution Unit (PDU) & Gantry Power Pan	➢ Volts: 380/400/420/440/460/480V, 3~ ➢ 50/60Hz ➢ Momentary 200KVA @ 0.85PF ➢ Continuous 40KVA	➢ Volts: 380/400/420/440/460/480V, 3~ ➢ 50/60Hz ➢ Momentary 200KVA @ 0.85PF ➢ Continuous 40KVA ➢ Additional Axial Boost Converter Board
Detector	➢ 160 mm wide ➢ 80 mm wide option ➢ 256 rows, 0.625 mm pixel pitch ➢ Low capacitance backlit photodiode ➢ Gemstone Scintillator Material ➢ Detector Thermal System (DTS) with fans	➢ 160 mm wide ➢ 80 mm wide option ➢ 256 rows, 0.625 mm pixel pitch ➢ Low capacitance backlit photodiode ➢ Gemstone Scintillator Material ➢ Detector Thermal System (DTS) with higher RPM fans

Determination of Substantial Equivalence

The Revolution Apex with 0.23 s/rot option has completed testing and is in compliance with IEC 60601-1 Ed. 3.1 and its associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25, XR-26, and XR-28. The proposed device has successfully completed all testing per our quality system. The risk management and design verification & validation activities did not raise any new questions about safety and effectiveness. The system 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:

- Requirement Definition
- Risk Analysis
- Technical Review
- Formal Design Review
- Code Inspection
- Testing on unit level (Module verification)
- Integration testing (Subsystem/System verification)
- Performance testing (Subsystem/System verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

GE believes the Revolution Apex with 0.23 s/rot is of comparable type and substantially equivalent to our currently marketed predicate device the Revolution CT Family (K191777).

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

Non-Clinical Testing

The performance evaluation testing included use of a cardiac phantom and mathematical modeling to provide technical substantiation of the 0.23 s/rot performance claims on the Revolution Apex Product Line. Various mathematical and statistical analyses were performed to demonstrate that each performance item was successfully verified and substantiated.

Clinical Testing

The Revolution CT family with 0.23 s/rot 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 LLC believes that the Revolution Apex with 0.23

s/rot option is as safe and effective, and performs in a substantially equivalent manner to the predicate device Revolution CT (K191777).