February 22, 2024

GE Hangwei Medical Systems Co., Ltd.
℅ Wenqing Tian
Lead Specialist, Regulatory Affairs
West Area of Building No 3, No.1 Yongchang North Road
Beijing Economic & Technological Development Area, Beijing 100176
CHINA

Re: K233749
Trade/Device Name: Revolution Ascend Sliding
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: January 23, 2024
Received: January 23, 2024

Dear Wenqing Tian:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233749

Device Name
Revolution Ascend Sliding

Indications for Use *(Describe)*
The system 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 image 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.

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.

K233749

510(k) Summary

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

Date:	November 22, 2023
Submitter:	GE Hangwei Medical System Co., Ltd. West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Technological Development Area, 100176 Beijing, P.R. China.
Primary Contact:	Wenqing Tian Lead Specialist, Regulatory Affairs Phone: +86-155-9370-8328 Email: Wenqing.TIAN@ge.com
Secondary Contacts:	Helen Peng Sr Regulatory Affairs Director Phone: 262-4248222 Email: hong.peng@med.ge.com Haibo He Regulatory Affairs Leader Phone: +86-010-5708-3413 Email: haibo.he1@ge.com
Proposed Device/ Device Trade Name:	Revolution Ascend Sliding
Device Classification:	Class II
Regulation Number/ Product Code:	21 CFR 892.1750 Computed Tomography X-ray System / JAK

Predicate Device Information

Device Name:	Revolution Ascend
Manufacturer:	GE Healthcare Japan Corporation
510(k) Number:	K213938, Cleared on February 4, 2022
Device Classification:	Class II

Regulation Number/ Product Code:	21 CFR 892.1750 Computed Tomography X-ray System / JAK

Reference Device Information

Device Name:	GE LightSpeed ACT FP16
Manufacturer:	GE Medical System, LLC
510(k) Number:	K091673
Device Classification:	Class II
Regulation Number/ Product Code:	21 CFR 892.1750 Computed Tomography X-ray System / JAK

Device Description

The proposed device Revolution Ascend Sliding is a head and whole-body CT system composed of a gantry, transporter, operator console with a host computer, power distribution unit, and interconnection cables. The system also includes image acquisition and reconstruction hardware/software, general system software, accompanying documents, and associated accessories/interconnections.

Revolution Ascend Sliding generates 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 modes.

CT is routinely used in interventional radiology (IR) and radiation oncology because it can provide outstanding spatial resolution and valuable geometric structure information for determining the treatment plan before a treatment procedure takes place. In some clinical scenarios in radiation oncology and/or IR, it is not optimal to transport a patient to a separate room and/or a separate table to get a diagnostic CT image. To simplify the clinical workflow, some hospitals desire to have the treatment procedure to be done in the CT suite where the clinicians can do CT imaging and the treatment procedure in the same room without moving the patient between rooms. To support such improved clinical workflow, we have modified predicate device Revolution Ascend (K213938) by mounting the gantry to a transporter which allows the gantry linear movement on rails in longitude direction to scan the desired region of interest instead of having the patient on a traditional CT tabletop (a.k.a. Cradle) that moves in and out of the gantry bore in the predicate device.

Revolution Ascend Sliding includes all the available features on predicate device (K213938) and maintains the identical/equivalent performance and image quality specifications. Its Intended Use and indications for use remain identical to those of the unmodified predicate device. Revolution Ascend Sliding remains compliant with IEC 60601-1 Ed. 3.2 and associated collateral and particular standards, NEMA XR25, XR26, XR28, and 21CFR Subchapter J performance standards.

Intended Use

The system is intended to be used for head, whole body 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 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

Revolution Ascend Sliding employs the same basic operating principles and fundamental technologies as the predicate device and reference device.

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

Subsystem	Revolution Ascend (Predicate Device, K213938)	Revolution Ascend Sliding (Proposed Device)
Gantry	Revolution Ascend Gantry - Bore size: 75cm - Physical Tilt Performix 40 Plus X-Ray Tube - Supports 40 mm beamwidth - Liquid Metal rotor bearing JEDI60DC High Voltage Generator - Peak Power: 72 kW -55 kW option (software limit on mA) NGX Collimator (75cm bore) - 40 mm max z-coverage Merc40H Detector - Backlit Diode technology - Chiclet Module design - GE low noise ASIC technology used for signal conversion	Revolution Ascend Sliding Gantry - Bore size: 75cm - **Physical Tilt: Disabled** Performix 40 Plus X-Ray Tube - Supports 40 mm beam width - Liquid Metal rotor bearing JEDI60DC High Voltage Generator - Peak Power: 72 kW NGX Collimator (75cm bore) - 40 mm max z-coverage Merc40H Detector - Backlit Diode technology - Chiclet Module design - GE low noise ASIC technology used for signal conversion

Patient Support	- VT1700v Table - Lite Table - Table accessories	Patient Support equipment is stationary in the horizontal axis, Gantry moves horizontally with rails system.
Horizontal movement	The patient table moves horizontally to the gantry bore during a CT exam while the gantry is stationary	The gantry mounted on a transporter moves horizontally on rails towards the patient who is positioned on a patient support device that is stationary. The transporter uses substantial design and manufacturing process as the reference device cleared in K091673.
Reconstruction	FBP ASIR-V (K133640) DLIR cleared with Revolution Ascend (K212067, K230807).	Same
Standards	IEC 60601-1 Ed. 3.1 IEC 60601-1-2 Ed 4.0 IEC 60601-1-3 Ed 2.1 IEC 60601-2-28 Ed 3.0 IEC 60601-2-44 Ed. 3.2 IEC 61223-3-5 Ed. 2.0 NEMA XR-25 NEMA XR-26 NEMA XR-28	**IEC 60601-1 Ed. 3.2** IEC 60601-1-2 Ed 4.0 **IEC 60601-1-3 Ed 2.2** IEC 60601-2-28 Ed 3.0 IEC 60601-2-44 Ed. 3.2 IEC 61223-3-5 Ed. 2.0 NEMA XR-25 NEMA XR-26 NEMA XR-28

The changes described above do not change the fundamental control mechanism, operating principle, energy type, and do not change the intended use from the predicate device Revolution Ascend.

Determination of Substantial Equivalence

The Revolution Ascend Sliding has completed testing and is in compliance with AAMI/ANSI ES 60601-1 and IEC60601-1 Ed. 3.2 and its associated collateral and particular standards, 21 CFR Subchapter J, and NEMA standards XR 25, XR 26, and XR 28. The device has successfully completed engineering design V &V and bench testing in support of substantial equivalence to the predicate device. The following quality assurance measures were applied to the development of the system:

- Risk Analysis and Control
- Required Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

GEHC believes the Revolution Ascend Sliding CT system is of comparable type and substantially equivalent to our currently marketed system Revolution Ascend (K213938).

Non-Clinical Testing

The verification and validation testing have been successfully completed as required by design control procedures under GE HealthCare's quality system. This includes risk management, software verification and validation testing as well as dose specifications and image quality testing in accordance with IEC 61223-3-5 ed.2 to demonstrate the overall system performance in a standardized and referenceable manner.

Non-clinical bench test results demonstrated the subject device performs equivalently to the predicate device.

Clinical Testing:

The Revolution Ascend Sliding CT system 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 HealthCare believes that the Revolution Ascend Sliding is as safe and effective, and performs in a substantially equivalent manner to the unmodified predicate device Revolution Ascend (K213938).