February 4, 2022

GE Healthcare Japan Corporation
% He Haibo
Regulatory Affairs Leader
7-127, 4-Chome, Asahigaoka,
Hino, Tokyo 191-8503
JAPAN

Re: K213938
Trade/Device Name: Revolution Ascend
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: December 15, 2021
Received: December 16, 2021

Dear He Haibo:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
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

K213938

Section 4: Indications for Use Statement

Revolution Ascend

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)*

K213938

Device Name
Revolution Ascend

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 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.

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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K213938
510(k) Summary

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

Date:	December 16th, 2021
Submitter:	GE Healthcare Japan Corporation 7-127, Asahigaoka, 4-chome Hino-shi, Tokyo, 191-8503, Japan
Primary Contact:	He Haibo Regulatory Affairs Leader Phone: +86-010-5708-3413 Email: haibo.he1@ge.com
Secondary Contacts:	Helen Peng Sr Regulatory Affairs Director Phone: 262-4248222 Email: hong.peng@ge.com Laura Turner Sr Regulatory Affairs Leader Phone: 262-200-1044 Email: laura.turner@ge.com
Proposed Device/ Device Trade Name:	Revolution Ascend
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:	K203169, Cleared on November 20, 2020
Device Classification:	Class II
Regulation Number/ Product Code:	21 CFR 892.1750 Computed Tomography X-ray System / JAK

Device Description

The Revolution Ascend is a head and whole-body CT system composed of a gantry, patient table, operator console with a host computer, power distribution unit, and interconnecting cables. The system also includes image acquisition and reconstruction hardware/software, general system software, accompanying documents, and associated accessories/interconnections. The system has a 75 cm gantry bore and 64-row detector.

Revolution Ascend 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.

A design change has been made to the Revolution Ascend with an alternative detector scintillator material prompting this premarket notification. While this change is being made, the design and manufacturing is such that the system performance remains identical to its unmodified predicate. The proposed device carries over all the features, options and specifications of the predicate device, including the Deep Learning Iterative Recon (DLIR) cleared via K212067 without change.

The proposed device ‘s Intended Use and Indications for Use remain identical to those of the unmodified predicate device. Revolution Ascend with the modified detector remains compliant with IEC 60601-1 Ed. 3.1 and associated collateral and particular standards, NEMA XR25, XR26, XR28, and 21 CFR 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 support, 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 employs the same basic operating principles and fundamental technologies as the predicate device.

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

Subsystem	**Revolution Ascend (Predicate Device, K203169)**	**Revolution Ascend (Proposed Device)**
Gantry	Revolution Ascend Gantry - Bore size: 75cm - Physical Tilt (± 30°) Performix 40 Plus X-Ray Tube - Supports 40 mm beamwidth - Liquid Metal rotor bearing JEDI60DC High Voltage Generator - Peak Power: 72 kW NGX Collimator (75cm bore) - 40 mm max z-coverage Merc40L Detector - Backlit Diode technology - Chiclet Module design - GE low noise ASIC technology used for signal conversion	Revolution Ascend Gantry - Bore size: 75cm - Physical Tilt (± 30°) 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 (with alternative material)** - Backlit Diode technology - Chiclet Module design - GE low noise ASIC technology used for signal conversion
Operator Console	NIO Console: - Host computer, keyboard, scan control unit, two monitors.	Same

Subsystem	Revolution Ascend (Predicate Device, K203169)	Revolution Ascend (Proposed Device)
Deep Learning Image Reconstruction (DLIR)	**DLIR cleared with Revolution Ascend (K212067).**	**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. 1.0 NEMA XR-25 NEMA XR-26 NEMA XR-28	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

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 has completed testing and in compliance with AAMI/ANSI ES 60601-1 and IEC60601-1 Ed. 3.1 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 between the subject device and predicate device. 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 Ascend CT system is of comparable type and substantially equivalent to our currently marketed system Revolution Ascend (K203169).

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

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 image quality performance evaluation using well established metrics and methods. IQ evaluation include:

- General IQ Performance testing in accordance with IEC 61223-3-5 Ed. 2 to demonstrate the overall system performance in a standardized and referenceable manner.
- Comparable IQ performance test using standard IQ, QA phantoms for typical conditions to demonstrate image quality equivalence of Revolution Ascend with Merc40H and predicate Revolution Ascend with Merc40L.
- Re-substantiation of the imaging performance associated with the cleared DLIR(K212067) on the subject device Revolution Ascend.

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

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 is as safe and effective, and performs in a substantially equivalent manner to the unmodified predicate device Revolution Ascend (K203169).