GE Healthcare Japan Corporation
% Helen Peng
Sr. Regulatory Affairs Director
GE Medical Systems, LLC
3000 North Grandview Blvd
WAUKESHA WI 53188

November 20, 2020

Re: K203169
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: October 22, 2020
Received: October 23, 2020

Dear Helen 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. 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)*
K203169

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.

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

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*"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

K203169

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

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

| | |
|---|---|
| Date: | October 22, 2020 |
| Submitter: | GE Healthcare Japan Corporation<br>7-127, Asahigaoka, 4-chome<br>Hino-shi, Tokyo, 191-8503, Japan |
| Primary Contact Person: | Tomohiro Ito<br>Sr. Regulatory Affairs Leader<br>Phone +81-42-585-5383 or +81-90-8346-6807<br>Email: tomohiro.ito@ge.com |
| Secondary Contact Persons: | Helen Peng<br>Sr Regulatory Affairs Director<br>GE Healthcare<br>Phone Number: 262-4248222<br>e-mail: hong.peng@ge.com |
| | John Jaeckle<br>Chief Regulatory Affairs Strategist<br>GE Healthcare<br>Phone Number: 262-424-9547<br>e-mail: John.Jaeckle.com |
| Product Identification | Revolution Ascend |
| Device Trade Name: | Revolution Ascend |
| Regulation Number / Classification: | Computed Tomography X-ray System, 21 CFR 892.1750 / Class II |
| Product Code: | 90-JAK |
| Manufacturer | GE Healthcare Japan Corporation<br>7-127, Asahigaoka, 4-chome |

| | |
|---|---|
| | Hino-shi, Tokyo, 191-8503, Japan |
| **Predicate Device Information:** | |
| Device Name | Revolution Maxima |
| 510 (K) number | K192686 cleared on October, 2019 |
| Regualation Number/ Classification | Computed Tomography X-ray System, 21 CFR 892.1750 / Class II |
| Product Code | 90-JAK |

**Marketed Devices:**

The Revolution Ascend is a CT device built upon the existing technologies of the predicate device, GE Healthcare' s currently marketed Computed Tomography X-ray System Revolution Maxima (K192686). It is of comparable type and substantially equivalent to Revolution Maxima. In addition, the system has the same intended use and indication for use as that of the predicate device. The system is labeled as the Revolution Ascend.

**Device Description:**

The Revolution Ascend CT system is head and whole body CT system incorporating the same basic fundamental operating principles as the predicate device. It is composed of a gantry, patient table, operator console, host computer, and power distribution unit (PDU), and interconnecting cables. The system also includes image acquisition and reconstruction hardware/software, general system software, accompanying documents, and associated accessories, interconnections. Its materials and construction are identical to our existing marketed products.

Identical to the predicate, 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. Revolution Ascend's Intended Use and Indications for Use remain identical to those of the predicate device.

Revolution Ascend includes virtually all the available features of the predicate device Revolution Maxima. Compared to the predicate, the changes incorporated into Revolution Ascend are primarily to introduce a widended bore gantry for easy handling of large patient, trauma examinations, interventional procedures and radiotherapy planning, and addition of other existing features already available from GE's other CT systems. These ported features include Auto Pilot workflow enabled by Deep learning based patient Auto Positioning, Intelligent Protocoling enabled by Machine Learning, Smart Plan and Auto Prescription all

integrated into the modern software platform and GUI adopted from Revolution CT, and cardiac feature Auto Gating and as well as Interventional feature 3D Guidance.

The performance and image quality specifications are substantially equivalent to the predicate. Revolution Ascend remains compliant with IEC 60601-1 Ed. 3.1 and associated collateral and particular standards, IEC 61223-3-5, 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 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 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** | **Predicate Device**<br>**Revolution Maxima (K192686)** | **Proposed Device**<br>**Revolution Ascend** |
|---|---|---|
| Gantry | Revolution Maxima gantry<br>- Bore: 70cm<br>- Digital Tilt (± 30°) | Revolution Ascend Gantry<br>- Bore: 75cm<br>- Physical Tilt (± 30°) |
| Patient Table | VT1700v, Lite | VT1700v, VT2000, VT2000x |
| GUI | Legacy platform | Revolution platform |
| 3D Guidance | Not Available | Available<br>*3D Guidance was cleared in K153429 and ported to proposed device |
| Smart Plan | Not Available | Available<br>*Smart Plan was cleared in K171013 and ported to proposed device |
| Auto Prescription | Not Available | Available<br>* Auto Prescription was cleared in K133705 and ported to proposed device |
| Auto Gating | Not Available | Available<br>* Auto Gating was cleared in K133705 and ported to proposed device |
| Intelligent Protocoling by Machine Learning | Not Available | Available<br>*workflow feature |
| Auto Positioning by Deep Learning | Available | Available |

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.

**Risk Analysis:**

Potential electrical, mechanical, and radiation hazards are identified in risk management including hazard analysis and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (UL/CSA and IEC60601-1 Ed.3.1 and associated collateral and particular standards for CT).

- Compliance to applicable CDRH 21 CFR subchapter J requirements.
- Compliance to NEMA XR 25, XR 26, and XR 28.

The device is designed and manufactured under the Quality System Regulations of 21 CFR 820 and ISO 13485.

**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 Maxima (K192686).

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

**Summary of Additional Testing**

***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 and dose performance evaluation using well established metrics and methods. IQ and dose evalauition include:

- Test using standard IQ, QA and ACR phantoms for standard conditions as well as challenging conditions such as with phantoms simulating large patients.
- Performance testing in accordance with IEC 61223-3-5 ed 2.
- 3D guidance test with phantoms simulating interventional conditions.

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

***Clinical Testing:***

The Revolution Ascend 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 is as safe and effective, and performs in a substantially equivalent manner to the predicate device Revolutiuon Maxima (K192686).