August 1, 2025

GE Medical Systems, LLC
℅ Haibo He
Sr. Lead Regulatory Affairs Specialist
3000 N Grandview Blvd.
WAUKESHA, WI 53188

Re: K250941
Trade/Device Name: Revolution Vibe
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: March 28, 2025
Received: June 24, 2025

Dear Haibo He:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K250941

Device Name
Revolution Vibe

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 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.

The CT system is indicated for low dose CT for lung cancer screening. The screening must be performed within the established inclusion criteria of programs/ protocols that have been approved and published by either a governmental body or professional medical society.

*Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information

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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510(k) Summary

K250941

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

Date:	June 23, 2025
Submitter:	GE Medical Systems, LLC 3000 N. Grandview Blvd. Waukesha, Wisconsin 53188.
Primary Contact:	Haibo He Sr. Regulatory Affairs Leader Email: haibo.he1@gehealthcare.com
Secondary Contacts:	Helen Peng Sr. Regulatory Affairs Director Phone: 262-424-8222 Email: hong.peng@gehealthcare.com
Proposed Device/ Device Trade Name:	Revolution Vibe
Device Classification:	Class II
Regulation Number/ Product Code:	21 CFR 892.1750 Computed Tomography X-ray System / JAK

Predicate Device Information

Device Name:	Revolution Apex Elite
Manufacturer:	GE Medical Systems, LLC
510(k) Number:	K213715, Cleared on December 17, 2021
Device Classification:	Class II
Regulation Number/ Product Code:	21 CFR 892.1750 Computed Tomography X-ray System / JAK

Device Description

This proposed device Revolution Vibe is a general purpose, premium multi-slice CT Scanning system consisting of a gantry, table, system cabinet, scanner desktop, power distribution unit, and associated accessories. It has been optimized for cardiac performance while still delivering exceptional imaging quality across the entire body.

Revolution Vibe is a modified dual energy CT system based on its predicate device Revolution Apex Elite (K213715). Compared to the predicate, the most notable change in Revolution Vibe is the modified detector design together with corresponding software changes which is optimized for cardiac imaging providing capability to image the whole heart in one single rotation same as the predicate.

Revolution Vibe offers an accessible whole heart coverage, full cardiac capability CT scanner which can deliver outstanding routine head and body imaging capabilities. The detector of Revolution Vibe uses the same GEHC's Gemstone scintillator with 256 x 0.625 mm row providing up to 16 cm of coverage in Z direction within 32 cm scan field of view, and 64 x 0.625 mm row providing up to 4 cm of coverage in Z direction within 50 cm scan field of view. The available gantry rotation speeds are 0.23, 0.28, 0.35, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, and 1.0 seconds per rotation.

Revolution Vibe inherits virtually all of the key technologies from the predicate such as: high tube current (mA) output, 80 cm bore size with Whisper Drive, Deep Learning Image Reconstruction for noise reduction (DLIR K183202/K213999, GSI DLIR K201745), ASIR-V iterative recon, enhanced Extended Field of View (EFOV) reconstruction MaxFOV 2 (K203617), fast rotation speed as fast as 0.23 second/rot (K213715), and spectral imaging capability enabled by ultrafast kilovoltage(kv) switching (K163213), as well as ECG-less cardiac (K233750). It also includes the Auto ROI enabled by AI which is integrated within the existing SmartPrep workflow for predicting Baseline and monitoring ROI automatically. As such, the Revolution Vibe carries over virtually all features and functionalities of the predicate device Revolution Apex Elite (K213715).

This CT system can be used for low dose lung cancer screening in high risk populations*.

* As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information

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 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.

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The CT system is indicated for low dose CT for lung cancer screening. The screening must be performed within the established inclusion criteria of programs/ protocols that have been approved and published by either a governmental body or professional medical society.

*Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information

Technology

Revolution Vibe 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 and the proposed device:

Subsystem	Revolution Apex Elite (Predicate Device, K213715)	Revolution Vibe (Proposed Device)
Gantry	➢ 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.	Same
Detector	➢ 160 mm Z-coverage ➢ 256 rows, 0.625 mm pixel pitch ➢ Low capacitance backlit photodiode ➢ Gemstone Scintillator Material ➢ Detector Thermal System (DTS) with higher RPM fans	➢ **Up to 160 mm in Z with 320 mm SFOV; Up to 40 mm in Z with up to 50 mm SFOV** ➢ **256 rows, 0.625 mm pixel pitch within 320 mm SFOV; 64 rows, 0.625 mm pixel within 500 mm SFOV** ➢ Low capacitance backlit photodiode ➢ Gemstone Scintillator Material ➢ Detector Thermal System (DTS) with higher RPM fans
Reconstruction	FBP ASIR-V (K133640) DLIR (K183202, K213999, K201745) MaxFOV 2 (K203617)	Same

The changes described above do not change the fundamental control mechanism, operating principle, energy type, and do not change the intended use, Patient Population or Contraindications from the predicate device Revolution Apex Elite.

Determination of Substantial Equivalence

The Revolution Vibe has completed testing and 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 between the subject device and predicate device. The following quality assurance measures were applied to the development of the system:

- Requirement Definition
- Risk Analysis and Control
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
    - Code Review
    - Software Unit Implementation
    - Software Integrations and Integration Testing
- System Testing
    - Safety Testing (Verification)
    - Image Performance Testing (Verification)
    - Simulating Use Testing (Validation)
- Software Release

The testing and results did not raise different questions of safety and effectiveness than associated with predicate device. We consider the proposed device is substantially equivalent to the predicate device, Revolution Apex Elite.

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.

Auto ROI performance was tested using 1341 clinical images from real clinical practice and the tests results in success rates exceeding the pre-established acceptance criteria.

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

Clinical Testing:

The clinical testing was carried out in the form of a reader study of sample clinical data. This is blinded, retrospective clinical reader study. 30 CT cardiac exams were evaluated by 3 readers who are US board-certified in Radiology with more than 5 years' experience in CT cardiac imaging. The exams covered a wide range of cardiac clinical scenarios. Readers were asked to provide evaluation of image quality and the

clinical utility. The result of this reader study validated that Revolution Vibe are of diagnostic utility and is safe and effective for its intended use.

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 Vibe is as safe and effective, and performs in a substantially equivalent manner to the unmodified predicate device Revolution Apex Elite (K213715).