April 2, 2024

GE Medical Systems, LLC.
℅ Katelyn Rowley
Sr. Lead Specialist - MICT
3000 N Grandview Blvd
WAUKESHA, WI 53188

Re: K233750
Trade/Device Name: ECG-less Cardiac
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 28, 2024
Received: February 28, 2024

Dear Katelyn 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 (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)*
K233750

Device Name
ECG-less Cardiac

Indications for Use *(Describe)*
ECG-less Cardiac streamlines patient preparation by enabling an alternative acquisition of cardiac CT images for general cardiac assessment without the need of a patient-attached ECG monitor. ECG-less Cardiac is for adults only.

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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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 22, 2022

Submitter: GE Medical Systems, LLC
3000 N. Grandview Blvd.
Waukesha, Wisconsin 53188

Primary Contact: Katelyn Rowley
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Device Trade Name: ECG-less Cardiac

Device Classification Class II

Regulation Number/ Product Code: 21 CFR 892.1750 Computed tomography x-ray system / JAK

Predicate Device Information

Device Name: Revolution CT Family

Manufacturer: GE Medical Systems, LLC

510(k) Number: K213715 cleared on December 17, 2021

Regulation Number/ Product Code: 21 CFR 892.1750 Computed tomography x-ray system / JAK

Device Description

ECG-less Cardiac is a software device that is an additional, optional cardiac scan mode that can be used on the Revolution Apex Elite, Revolution Apex, and Revolution CT with Apex edition systems. There is no change to the predicate device hardware to support the subject device. Currently, the available cardiac scan modes on the Revolution CT Family are Cardiac Axial and Cardiac Helical, which

makes use of an ECG signal to physiologically trigger the cardiac acquisitions and/or to retrospectively gate the reconstruction.

ECG-less Cardiac is a third cardiac scan mode that introduces the ability to acquire cardiac images without the need of a patient-attached ECG monitor. Hence, an ECG signal from the patient is not utilized for this scan mode. The ECG-less Cardiac workflow leverages the full-heart coverage capability of 160 mm configurations, fast gantry speeds (0.28 and 0.23 s/rot), and existing cardiac software options of SmartPhase and SnapShot Freeze 2 (K183161) to acquire images that are suitable for coronary and cardiac functional assessment.

The ECG-less cardiac feature allows the user to acquire a cardiac CT scan without the need to complete the steps associated with utilizing an ECG monitor, such as attaching ECG electrodes to the patient, checking electrode impedance, and confirming an ECG trace is displayed on the operator console, thus optimizing the workflow.

ECG-less Cardiac may be best utilized in examinations where excluding the ECG connection would streamline the patient examination, including loading and unloading of the patient. This may result in an improved workflow for certain clinical presentations. ECG-less Cardiac may also increase access to cardiac assessment for patients that are difficult to receive an ECG signal from. Circumstances where the subject device is expected to increase cardiac access includes scenarios where trauma patient has a diagnostic ECG attached and/or other instrumentation, such that there is added difficulty of attaching ECG leads for a gated scan, and situations where it is challenging to get an ECG signal from a patient such as a patient's t-wave triggering the scan or R-peak being difficult to detect.

Indications for Use

ECG-less Cardiac streamlines patient preparation by enabling an alternative acquisition of cardiac CT images for general cardiac assessment without the need of a patient-attached ECG monitor. ECG-less Cardiac is for adults only.

Comparisons

ECG-less Cardiac on the Revolution CT Family is substantially equivalent to the predicate device Revolution Apex (K213715). ECG-less Cardiac largely utilizes existing CT system scan technology. The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device. The changes described below do not change the fundamental technology of the predicate and do not raise any issues of safety and effectiveness.

Specification/ Attribute	**Revolution CT Family** **(Predicate Device, K213715)**	**ECG-less Cardiac** on the Revolution CT Family **(Proposed Device)**
Cardiac Scan Modes	Cardiac Axial with ECG gating Cardiac Helical with ECG gating	New **ECG-less Cardiac scan mode** to the predicate device in addition to the existing Cardiac Axial and Cardiac Helical modes with ECG gating
CT Hardware	Revolution CT Family System including CT Gantry, Patient Table, Data Acquisition System, and operator console computer	Same as predicate. (ECG-less Cardiac is a software only application implemented into operator console computer)
Compatible Cardiac Rotation Speeds	0.23, 0.28, and 0.35 s/rot	ECG-less Cardiac: 0.23 and 0.28 s/rot
Supported Cardiac Collimation	Cardiac Axial: 40, 80, 100, 120, 140, 160 mm Cardiac Helical: 40 mm	ECG-less Cardiac: 120, 140, and 160 mm

Determination of Substantial Equivalence

Summary of Non-Clinical Testing

ECG-less Cardiac has successfully completed the design control activities including risk management, verification and validation testing per our quality system. No additional hazards were identified, and no unexpected test results were observed. ECG-less Cardiac was designed under GE HealthCare's QMS per the Quality System Regulations of 21CFR 820 and ISO 13485.

The following quality assurance measures have been 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, the Revolution CT Family.

The non-clinical testing also included engineering bench testing that was carried out to assess how simulated ECG-less Cardiac scan conditions performed against an ECG-gated "ground truth" nominal phase location. This testing included a variety of cases that are representative of the clinical scenarios where ECG-less Cardiac is intended to be used. Non-clinical testing also concluded the dose level of ECG-less Cardiac acquisition is comparable to Cardiac Helical and single peak mA, full heart cycle Cardiac Axial as commonly used for functional assessment. The result of the engineering bench testing showed that ECG-less Cardiac scan acquisitions can produce images that are equivalent to an ECG-gated "ground truth" nominal phase location and is safe and effective for its intended use.

Clinical Testing

The clinical testing was carried out in the form of a reader study of sample clinical data. The reader study included prospectively collected clinical data from patients undergoing a routine cardiac exam that represented a broad variety of technical scan parameters and patient characteristics, such as their clinical indication, heart rate, age, and size. Each image was read by three board certified radiologists who specialize in cardiac imaging who provided an assessment of image quality related to motion artifact and diagnostic use according to a Likert scale. These images generated from ECG-less Cardiac acquisitions were consistently rated as interpretable without a significant motion artifact penalty. Thus, the result of this reader study validated that ECG-less Cardiac acquisitions are of diagnostic utility and is safe and effective for its intended use.

Substantial Equivalence

The changes associated with ECG-less Cardiac do not change the Intended Use from the predicate and represent equivalent technology.

ECG-less Cardiac was developed under GE Healthcare's quality system. Design verification, along with bench testing and the clinical reader study provided in this submission demonstrates that ECG-less Cardiac is substantially equivalent and hence as safe and as effective as the legally marketed predicate device. GE's quality system's design, verification, and risk management processes did not identify any unexpected results, or adverse effects stemming from the changes to the predicate.

GE Healthcare believes that ECG-less Cardiac is substantially equivalent to the predicate device and hence is safe and effective for its intended use.