August 1, 2024

GE Medical Systems SCS
c/o Peter Uhlir
Regulatory Affairs Program Manager
283 Rue De La Miniere
Buc, 78530
FRANCE

Re: K233731
Trade/Device Name: CardIQ Suite
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK, QIH
Dated: November 21, 2023
Received: July 3, 2024

Dear Peter Uhlir:

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,

Gabriela M. Rodal -S

Digitally signed by Gabriela M. Rodal -S

for

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)*
K233731

Device Name
CardIQ Suite

Indications for Use *(Describe)*

CardIQ Suite is a non-invasive software application designed to provide an optimized application to analyze cardiovascular anatomy and pathology based on 2D or 3D CT cardiac non contrast and angiography DICOM data from acquisitions of the heart. It provides capabilities for the visualization and measurement of vessels and visualization of chamber mobility. CardIQ Suite also aids in diagnosis and determination of treatment paths for cardiovascular diseases to include, coronary artery disease, functional parameters of the heart, heart structures and follow-up for stent placement, bypasses and plaque imaging.
CardIQ Suite provides calcium scoring, a non-invasive software application, that can be used with non-contrasted cardiac images to evaluate calcified plaques in the coronary arteries, heart valves and great vessels such as the aorta. The clinician can use the information provided by calcium scoring to monitor the progression/regression of calcium in coronary arteries over time, and this information may aid the clinician in their determination of the prognosis of cardiac disease.

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.

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510(k) Summary – K233731

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

Date:	July 31, 2024
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Peter Uhlir Regulatory Affairs Program Manager GE HealthCare Tel: (+36) 70-436-9317 Email: peter.uhlir@ge.com
Secondary Contact Person:	Elizabeth Mathew Senior Regulatory Affairs Manager GE HealthCare Tel: 262-424-7774 Email: Elizabeth.Mathew@ge.com
Device Trade Name:	CardIQ Suite
Common/Usual Name:	System, X-Ray, Tomography, Computed
Primary Classification name: Primary Regulation Number: Primary Product Code: Secondary Product Code: Classification:	Computed tomography x-ray system 21 CFR 892.1750 JAK QIH Class II

Primary Predicate Device	
Device name:	CardIQ Suite
Common/Usual Name:	System, X-Ray, Tomography, Computed
Manufacturer:	GE Medical Systems SCS
510(k) number:	K213725
Classification Name:	Computed tomography x-ray system
Regulation Number:	21 CFR 892.1750
Product Code:	JAK
Classification:	Class II
Reference Device	
Device name:	CardIQ Xpress 2.0
Common/Usual Name	System, X-Ray, Tomography, Computed
Manufacturer:	GE Medical Systems SCS
510(k) number:	K073138
Classification Name:	Computed tomography x-ray system
Regulation Number:	21 CFR 892.1750
Product Code:	JAK
Classification:	Class II

Device Description:

CardIQ Suite is a non-invasive software application designed to work with DICOM CT data acquisitions of the heart. It is a collection of tools that provide capabilities for generating measurement's both automatically and manually, displaying images and associated measurements in an easy-to-read format and tools for exporting images and measurements in a variety of formats.

CardIQ Suite provides an integrated workflow to seamlessly review calcium scoring and coronary CT angiography (CCTA) data. Calcium Scoring has the capability to automatically segment and label the calcifications within the coronary arteries, and then automatically compute a total and per territory calcium score. The calcium segmentation/labeling is using a new deep learning algorithm. The calcium scoring is based on the standard Agatston/Janowitz 130 (AJ 130) and Volume scoring methods for the segmented calcific regions. The software also provides the users a manual calcium scoring capability that allows them to edit (add/delete or update) auto scored

lesions. It also allows the user to manually score calcific lesions within coronary arteries, aorta, aortic valve and mitral valve as well as other general cardiac structures. Calcium scoring offers quantitative results in the AJ 130 score, Volume and Adaptive Volume scoring methods.

Calcium Scoring results can be exported as DICOM SR to assist with integration into structured reporting templates. Images can be saved and exported for sharing with referring physicians, incorporating into reports and archiving as part of the CT examination.

The Multi-Planar Reformat (MPR) Cardiac Review and Coronary Review steps provide an interactive toolset for review of cardiac exams. Coronary CTA datasets can be reviewed utilizing the double oblique angles to visually track the path of the coronary arteries as well as to view the common cardiac chamber orientations. Cine capability for multi-phase data may be useful for visualization of cardiac structures in motion such as chambers, valves and arteries, automatic tracking and labeling will allow a comprehensive analysis of the coronaries. Distance measurement and ROI tools are available for quantitative evaluation of the anatomy.

Intended Use:

CardIQ Suite is a collection of non-invasive software features intended to analyze CT cardiovascular anatomy and pathology and aid in determining treatment paths.

Indication for Use:

CardIQ Suite is a non-invasive software application designed to provide an optimized application to analyze cardiovascular anatomy and pathology based on 2D or 3D CT cardiac non contrast and angiography DICOM data from acquisitions of the heart. It provides capabilities for the visualization and measurement of vessels and visualization of chamber mobility. CardIQ Suite also aids in diagnosis and determination of treatment paths for cardiovascular diseases to include, coronary artery disease, functional parameters of the heart, heart structures and follow-up for stent placement, bypasses and plaque imaging.

CardIQ Suite provides calcium scoring, a non-invasive software application, that can be used with non-contrasted cardiac images to evaluate calcified plaques in the coronary arteries, heart valves and great vessels such as the aorta. The clinician can use the information provided by calcium scoring to monitor the progression/regression of calcium in coronary arteries over time, and this information may aid the clinician in their determination of the prognosis of cardiac disease.

Technology:

The proposed device CardIQ Suite employs the same fundamental scientific technology as its predicate and reference devices.

Comparison:

The table below summarizes the key feature/technological differences and similarities between the predicate devices:

Specification	Primary Predicate Device: CardIQ Suite (K213725)	Subject Device: CardIQ Suite	Comparison
Input Data for Calcium Scoring	Image Requirements: * 120kVp * Gated cardiac acquisition * DFOV - 24 cm - 26 cm * Slice thickness ≤ 3mm * Non-contrast	Image Requirements: * 120kVp * Gated cardiac acquisition * DFOV - 24 cm - 35 cm * Slice thickness ≤ 3mm * Non-contrast	**Substantially equivalent.** The only modification in the subject device comes from the DFOV limitation that has been adjusted to be less restrictive.
Segmentation and labeling calcific regions in the coronaries	Yes, Automated using deep learning algorithm	Yes, Automated using deep learning algorithm	**Identical**
Manual Segmentation and labeling of calcific regions	Yes	Yes	**Identical**
Labeling of calcifications	The software provides the following labels for the coronary arteries according to regional territories. • LAD territory: Left Main Artery (LMA), Ramus Intermedius Branch (RIB), Left Anterior Descending (LAD) and all Diagonal branches. • LCX territory: Left Circumflex artery (LCX) and all Obtuse marginal branches. • RCA territory: Right Coronary Artery (RCA), Posterior Descending Artery (PDA) and	The software provides the following labels for the coronary arteries according to regional territories. • LAD territory: Left Main Artery (LMA), Ramus Intermedius Branch (RIB), Left Anterior Descending (LAD) and all Diagonal branches. • LCX territory: Left Circumflex artery (LCX) and all Obtuse marginal branches. • RCA territory: Right Coronary Artery (RCA), Posterior Descending Artery (PDA) and	**Identical**

Specification	Primary Predicate Device: CardIQ Suite (K213725)	Subject Device: CardIQ Suite	Comparison
	Posterior Lateral Branch (PLB).	Posterior Lateral Branch (PLB).	
Computation of Agatston score	Yes	Yes	**Identical**
Calcium Score – Volume Scoring Method	Yes, Volume and Adaptive Volume	Yes, Volume and Adaptive Volume	**Identical**

Specification	Primary Predicate Device: CardIQ Suite (K213725)	Subject Device: CardIQ Suite	Comparison
Cardiac Review	Coronary 2D Review is intended to assist readers in the review of coronary artery imaging. Within this review step, readers will find tools aligned with a 2D coronary artery CTA review as well as general overview of all reconstructions acquired within a study such a multi-phase cine acquisitions or delayed enhancement imaging. It provides various review tools: * Multi oblique tools to generate chamber, vessel or lesion views in any desired orientations * Cine mode to view multi-phase data in motion * 2D distance, ROI * Rendering Note: A segmented 3D Volume Rendering model of the heart is not available.	Coronary 2D Review is renamed as 'MPR Cardiac Review' and has the same intended purpose as the predicate device which is intended to assist readers in the review of coronary artery imaging. Within this review step, readers will find tools aligned with a 2D coronary artery CTA review, a segmented 3D Volume Rendering model of the heart (NEW), as well as general overview of all reconstructions acquired within a study such a multi-phase cine acquisitions or delayed enhancement imaging. It provides various review tools: * Multi oblique tools to generate chamber, vessel or lesion views in any desired orientations * Cine mode to view multi-phase data in motion * 2D distance, ROI * Rendering	**Substantially equivalent.** The only difference in the subject device is the introduction of a new deep learning algorithm to automatically segment heart and provide a segmented 3D Volume Rendering model of the heart. The functionality to segment heart in 3D already exists in the reference device CardIQ Xpress 2.0 (K073138). The reference device uses mathematical morphology operations and Hounsfield Unit based thresholds to segment the heart in 3D. In the subject device, a fully convolutional neural network trained and validated on annotated CT images is used to segment the heart. From the user perspective the output of the segmentation, the editing capability and workflow remains the same between the subject device and reference device. The main reason to incorporate the deep learning algorithm is to improve the workflow efficiency.

Specification	Primary Predicate Device: CardIQ Suite (K213725)	Subject Device: CardIQ Suite	Comparison
Data Export	CardIQ Suite provides a variety of methods for sharing the results with clinical partners. * Calcium Score results and scored images can be saved as DICOM SR series and networked to DICOM destinations for structured reporting purposes. * Copy individual images or the results table to paste into personalized communications. * Screen capture individual images and results to save data pertinent to the patient file for selective archiving needs. * Generate file for importing into customized report templates or research file management needs * Export selected Images	CardIQ Suite provides a variety of methods for sharing the results with clinical partners. * Calcium Score results and scored images can be saved as DICOM SR series and networked to DICOM destinations for structured reporting purposes. * Copy individual images or the results table to paste into personalized communications. * Screen capture individual images and results to save data pertinent to the patient file for selective archiving needs. * Generate file for importing into customized report templates or research file management needs * Export selected Images	**Identical**
Coronary Review step	No	Yes	**Substantial Equivalent** Deep-Learning Algorithms are incorporated in the subject device to automatically segment coronary, automatically track and label coronary centerline in order to improve workflow efficiency. The same functionalities already exist in the reference device CardIQ Xpress 2.0 (K073138), the difference is in how the functionality is

Specification	Primary Predicate Device: CardIQ Suite (K213725)	Subject Device: CardIQ Suite	Comparison
			implemented in the devices. For the Coronary tree segmentation, the reference device, CardIQ Xpress 2.0 (K073138) utilizes signal processing methods to achieve coronary segmentation, whereas in the subject device a deep-learning based algorithm is implemented to perform the same function. For the Coronary centerline tracking, the reference device CardIQ Xpress 2.0 utilizes mathematical morphology, leveraging on hessian filters and ray tracing to provide the coronary centerline tracking, whereas in the subject device a deep-learning based algorithm is implemented to perform the same function. The prerequisite for this algorithm is that the Coronary tree segmentation must be performed. For the Coronary labeling, the reference device CardIQ Xpress 2.0 utilizes a rules-based algorithm, based on the knowledge of the anatomy of the coronaries, whereas in the subject device a deep-learning based algorithm is implemented to perform the same function. The prerequisite for this algorithm is that the Coronary tree segmentation and Coronary centerline tracking must be performed. From the user perspective the output of the coronary segmentation, tracking and labeling, the editing capability for coronary segmentation, tracking and labeling and the workflow remains the same between the subject device and reference device. The main reason to incorporate the deep learning algorithms is to improve the workflow efficiency.

Determination of Substantial Equivalence:

Summary of Non-Clinical, Design Control Testing

CardIQ Suite has successfully completed the design control testing per GE's quality system. It was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. No additional hazards were identified, and no unexpected test results were observed. The proposed device complies with NEMA PS 3.1 - 3.20 (2022) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard.

The following quality assurance measures were applied to the development of the device:

- Requirements Definition
- Risk Analysis
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
- Performance testing (Verification, Validation)
- Safety Testing (Verification)

The proposed CardIQ Suite has been successfully verified on the AW Server platform. All the testing and results did not raise new or different questions of safety and effectiveness other than those already associated with predicate devices. The documentation level was determined to be Basic Documentation Level.

In addition, Engineering has performed bench testing for the four newly introduced deep learning algorithms in the subject device for automated heart segmentation, coronary segmentation, coronary centerline tracking and coronary labeling, using a database of retrospective CT exams. This database of exams is representative of the clinical scenarios where CardIQ Suite is intended to be used, with consideration of acquisition protocols and clinical indicators. The result of the algorithm validation showed that the algorithm successfully passed the defined acceptance criteria.

Summary of Clinical Testing

A reader study evaluation was performed with a sample of clinical CT images which were processed with the CardIQ Suite software. The purpose of this study was to evaluate the output of the automated Heart Segmentation, Coronary Tree Segmentation, Coronary Centerline Tracking and Coronary Artery Labeling using the Likert Scales and Additional Grading Scales. The reader evaluation concluded that the automated outputs provided by the Heart Segmentation, Coronary Tree Segmentation, Coronary Centerline tracking and Coronary Labeling algorithms incorporated in the subject device CardIQ Suite were scored to be acceptable by the readers for greater than 90% of the exams which had good image quality. Based on the reader study evaluation, we conclude that the automation of Heart Segmentation, Coronary Tree Segmentation, Coronary Centerline Tracking and Coronary Artery Labeling provides an improvement in workflow efficiency when compared to the predicate and reference devices wherein these functionalities were performed manually by the user or using traditional algorithms.

Conclusion:

CardIQ Suite has substantial equivalent technological characteristics as its predicate devices.

GE's quality system's design, verification, and risk management processes did not identify any new questions of safety or effectiveness, hazards, unexpected results, or adverse effects stemming from the changes to the predicates.

Based on development under GE HealthCare's quality system, successful design verification, software documentation for a "Basic Documentation Level", along with the engineering bench testing and reader study, GE HealthCare believes that the proposed CardIQ Suite is substantially equivalent to, and hence as safe and as effective for its Intended Use as the legally marketed predicate device.