June 18, 2025

GE Medical Systems SCS
℅ Mireille Haddad
Regulatory Affairs Program Manager
283, rue de la Miniere
BUC, 78530
FRANCE

Re: K243672
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 27, 2024
Received: May 19, 2025

Dear Mireille Haddad:

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,

FDA Digitally signed by Gabriela M. Rodal -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243672

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 overtime, and this information may aid the clinician in their determination of the prognosis of cardiac disease. CardIQ Suite also provides an estimate of the volume of heart fat for informational use.

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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K243672

510(k) Summary

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

Date:	May 16, 2025
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Mireille Haddad Regulatory Affairs Program Manager GE HealthCare Email: mireillehaddad@gehealthcare.com
Secondary Contact Person:	Elizabeth Mathew Senior Regulatory Affairs Manager GE HealthCare Tel: 262-424-7774 Email: elizabeth.mathew@gehealthcare.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:	K233731
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 name:	**SmartScore 4.0**
Common/Usual Name:	System, X-Ray, Tomography, Computed
Manufacturer:	GE Medical Systems SCS
510(k) number:	K020929
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 measurements 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 a fully automatic capability which will detect calcifications within the coronary arteries, label the coronary arteries according to regional territories and generate a total and per territory calcium score based on the AJ 130 and Volume scoring methods. Interactive tools allow editing of both the auto scored coronary lesions and other calcified lesions such as aortic valve, mitral valve as well as other general cardiac structures. Calcium scoring results can be compared with two percentile guide databases to better understand a patient's percentage of risk based on age, gender, and ethnicity. Additionally, for these non-contrasted exams, the heart fat estimation automatically estimates values within the heart that constitute adipose tissue, typically between –200 and –30 Hounsfield Units.

Calcium Scoring results can be exported as DICOM SR, batch axial SCPT, or a PDF report 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. Vessel lumen diameter is calculated, and the minimum lumen diameter computed is shown in color along the lumen profile.

Distance measurement and ROI tools are available for quantitative evaluation of the anatomy. Vascular findings of interest can be identified and annotated by the user, and measurements can be calculated for centerline distances, cross-sectional diameter and area, and lumen minimum diameter.

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. CardIQ Suite also provides an estimate of the volume of heart fat for informational use.

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 (**K233731**)**	**Subject Device:** **CardIQ Suite**	**Comparison**
Input Data for Calcium Scoring	Image Requirements: • 120kVp • Gated cardiac acquisition • DFOV - 24 cm - 35 cm • Slice thickness ≤ 3mm • Non-contrast	Image Requirements: • 120kVp • Gated cardiac acquisition • DFOV - 24 cm - 35 cm • Slice thickness ≤ 3mm • Non-contrast	**Identical**
Segmentation and labeling calcific regions in the coronaries	Yes	Yes	**Identical**

Specification	Primary Predicate Device: CardIQ Suite (K233731)	Subject Device: CardIQ Suite	Comparison
Manual Segmentation and labeling of calcific regions	Yes	Yes	**Identical**
Computation of calcium score - Agatson Score & Volume Scoring methods	Yes	Yes	**Identical**
Percentile guide	No	Yes	**Substantially Equivalent** In the subject device, the calcium score is used as input to a percentile guide in order to be able to compare the patient's calcium score with a similar population of individuals. Though the percentile guide functionality does not exist in the predicate device, this functionality already exists in the reference device, SmartScore 4.0 (K020929).
Cardiac Review	Yes	Yes	**Identical** MPR Cardiac 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, a segmented 3D Volume Rendering model of the heart, as well as general overview of all reconstructions acquired within a study such a multi-phase cine acquisitions or delayed enhancement imaging.

Specification	Primary Predicate Device: CardIQ Suite (K233731)	Subject Device: CardIQ Suite	Comparison
Heart Segmentation	Yes (Contrast-enhanced cardiac exams)	Yes (Contrast-enhanced and non-contrast cardiac exams)	**Substantial Equivalent** The predicate device already segments the heart for contrast-enhanced exams and the same algorithm exists in the subject device with no changes. The subject device has been updated to add another deep learning algorithm to segment non-contrasted heart exams. The new deep learning algorithm for heart segmentation of non-contrasted exams uses the same model as the previous existing heart segmentation algorithm for contrasted exams, however now the input is changed, and the model is trained and tested with the non-contrasted exams.
Heart fat estimate	No	Yes	**Substantial Equivalent** In the subject device, a predefined HU threshold of -200 to 30 is applied to the ROI and is automatically generated on the segmented heart which provides the visualization of the heart fat estimate. The estimated volume of the heart fat is calculated for the designated CACS phase selected. In the reference device, CardIQ Xpress 2.0, the same functionality can be performed using semi-automatic segmentation tools.
Coronary Review - Coronary Segmentation	Yes	Yes	**Identical**

Specification	Primary Predicate Device: CardIQ Suite (K233731)	Subject Device: CardIQ Suite	Comparison
Coronary Review - Coronary Tracking	Coronary Centerline Tracking is available	Coronary Centerline Tracking is available, includes lumen segmentation.	**Substantially equivalent** The functionality of coronary centerline tracking already exists in the predicate device CardIQ Suite. In the subject device, a new post-processing step is added to the coronary centerline tracking algorithm to generate a new output: the coronary lumen segmentation. The lumen segmentation was already available in the reference device CardIQ Xpress 2.0. The post-processing lumen segmentation added in the subject device uses the same image processing methodology, based on pixel intensity, that was used in CardIQ Xpress 2.0. Additionally, the Deep learning algorithm for coronary tracking in the subject device has been updated by retraining to a finer resolution for more precision and incorporates some post-processing steps to refine the centerline and tracking at vessel ostia, aorta, and vessel bifurcations.
Coronary Review - Coronary Labeling	Yes	Yes	**Substantially equivalent** The functionality of coronary centerline labelling already exists in the predicate device. The algorithm coronary labelling has been improved to increase the performance but uses a similar approach as the one in the predicate device.

Specification	Primary Predicate Device: CardIQ Suite (K233731)	Subject Device: CardIQ Suite	Comparison
Lumen diameter Quantification and minimum diameter computations Estimate (Narrowing Highlights)	No	Yes	**Substantial Equivalent** The lumen diameter quantification is calculated using a new non-deep learning algorithm and displayed as a lumen minimum diameter profile graph. This profile is equivalent to the minimum diameter lumen profile available in the reference device, CardIQ Xpress 2.0 (K073138). A local reduction in minimum diameter in the lumen profile is color coded based on a signal processing algorithm.
Vascular Measurement Tool	No	Yes	**Substantial Equivalent** The computational method and user workflow for vascular measurements in the subject device, is identical to the reference device, CardIQ Xpress 2.0 (K073138).

Determination of Substantial Equivalence:

Summary of Non-Clinical and Clinical , Design Control Testing

CardIQ Suite has successfully completed the design control testing per GE HealthCare'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 new and modified algorithms in the subject device, using a database of retrospective CT exams. These exams were collected from different clinical sites, with a variety of acquisition parameters, and pathologies. This database is representative of the clinical scenarios where the proposed device will be used, encompassing variations in acquisition parameters, image quality, pathologies, and anatomy.

- For the New Heart Segmentation deep learning algorithm for non-contrast CT exams, the output has met the acceptance criteria of more than 90 % of the exams that are successfully segmented based on testing performed on 111 CT exams.
- For the New Heart Fat volume estimate algorithm (non-deep learning), the automated estimate of the volume of heart fat was deemed acceptable as the average Dice score is greater than or equal to 90% based on testing performed on 111 CT exams. Under or over estimation of the heart fat volume estimate may be the result of inaccurate heart segmentation. Heart fat volume estimate is for informational use.

- A new algorithm was developed for lumen diameter quantification (non deep learning). Its performance was evaluated on 94 CT exams with a total of 353 narrowings across all available test sets by comparing its estimated diameters to those from the reference device CardIQ Xpress 2.0 (K073138). The mean absolute difference is lower than the mean voxel size, demonstrating sufficient agreement for lumen quantification.

- The bench testing performed for the modified algorithms of the Coronary Centerline

Tracking and Coronary Centerline Labeling, has proven that the performance of these algorithms is enhanced when compared to the predicate device.

In conclusion, the validation results for the new and modified algorithms met the defined acceptance criteria.

Conclusion:

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

GE HealthCare'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 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.