July 21, 2026

GE Medical Systems SCS
% Haddad Mireille
Regulatory Affairs Program Manager
283, Rue De La Miniere
BUC, 78530
FRANCE

Re: K253770
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 25, 2025
Received: June 22, 2026

Dear Haddad Mireille:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253770

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. 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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K253770 510(k) Summary

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

Date:	June 19, 2026
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 Director - Regulatory Affairs 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:	K243672
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 name:	**Spine Auto Views**
Common/Usual Name:	System, X-Ray, Tomography, Computed
Manufacturer:	GE Medical Systems SCS
510(k) number:	K223424
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:

Table 1 below summarizes the key feature/technological differences and similarities between the predicate devices.

Table 1: Key differences and similarities between the predicate devices.

Specification	**Primary Predicate Device: CardIQ Suite (**K243672**)**	**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 of calcifications in the coronary arteries	Automated using deep learning algorithm	Automated using deep learning algorithm	**Identical**
Manual segmentation and labeling of calcifications in the heart	Available	Available	**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 Posterior Lateral Branch (PLB).	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 Posterior Lateral Branch (PLB).	**Identical**
Computation of Agatston score calcium score	Available	Available	**Substantially Equivalent** A rounding adjustment has been made in the subject device to minimize imprecision effects during the computation.
Calcium Score – Volume Scoring Method	Available (Volume and Adaptive Volume).	Available (Volume and Adaptive Volume).	**Identical**
Percentile Guide	Available (GE HealthCare and MESA)	Available (GE HealthCare and MESA)	**Identical**
Heart Segmentation	Available (Contrast enhanced and non-contrast enhanced)	Available (Contrast enhanced and non-contrast enhanced)	**Identical**
Heart Fat Estimate	Available	Available	**Identical**

Cardiac Review	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. 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	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. 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	**Identical**
Coronary Review - Coronary Segmentation	Available	Available	**Identical**
Lumen diameter Quantification and minimum diameter coloring	Available	Available	**Identical**
Vascular Measurement Tool	Available	Available	**Identical**

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 •Calcium Score results and scored images can be saved as PDF series •Screen capture batch images and results to save data pertinent to the patient file for selective archiving needs.	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 •Calcium Score results and scored images can be saved as PDF series •Screen capture batch images and results to save data pertinent to the patient file for selective archiving needs.	**Identical**
DICOM SR Reload	Available	Available	**Identical**
Coronary Review - Coronary Tracking and Lumen Segmentation	Available	Available	**Substantially equivalent** Tracking algorithm remains the same in the subject device when compared to the predicate device. Lumen segmentation algorithm has been modified from an image processing approach, present in the predicate device to a deep learning-based method. The algorithms were evaluated by validating lumen diameter quantification as it integrates tracking and lumen segmentation algorithms. The key performance indicator, mean absolute difference diameter (MAD) in lumen diameter was consistently low across both the predicate device and subject device.
Coronary Review -	Available	Available	**Substantially equivalent** In the subject device the Coronaries

Coronary Labelling			Labelling Deep Learning algorithm reflects a shift in architectural approach and performance refinement. Comparison testing was conducted between the predicate and subject devices, and the testing concluded that the performance of the algorithm in the subject device is enhanced when compared to the predicate device.
Cardiac Auto Views – CACS Auto Views	Not Available	Calcium scoring batch results can be automatically generated and sent to a DICOM destination of the user's choosing.	**Substantially equivalent** In the subject device, the same clinical outputs as the predicate device can be automatically generated and can be sent directly to a user configured DICOM destination.
Cardiac Auto Views - Coronaries Auto Views	Not Available	Coronary batch results can be automatically generated and sent to a DICOM destination of the user's choosing.	**Substantially equivalent** A new capability of automatically generating coronary reformats is introduced in the subject device, the same capability already exists in the reference device, CardIQ Xpress 2.0 (K073138). Additionally, a new capability of automatically sending the reformatted images to a user defined DICOM destination is new to the subject device, but already exists in the reference device, Spine Auto Views (K223424). Reference device, Spine Auto Views, generates anatomically focused multi-planar reformats and automatically exports these results to user defined DICOM destinations.

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 the 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.

- Coronaries Tracking and Lumen Segmentation Algorithm - Tracking algorithm remains the same in the subject device as to the predicate device. Lumen segmentation algorithm has been modified from an image processing approach, present in the predicate device CardIQ Suite (K243672) to a deep learning-based method. The algorithms were evaluated by validating lumen diameter quantification as it integrates tracking and lumen segmentation algorithms. Validation was performed on 75 CT exams with a total of approximately 500 annotated vessel branches. The key performance indicator, mean absolute difference diameter (MAD) in lumen diameter was consistently low across both the predicate device and subject device.

- Coronary Labelling Algorithm - This is a deep learning-based algorithm. In the subject device the Coronaries Labelling Deep Learning algorithm reflects a shift in architectural approach and performance refinement. Comparison testing was conducted between the predicate and subject devices, and the testing concluded that the performance of the algorithm in the subject device is enhanced when compared to the predicate device.

Predetermined Change Control Plan (PCCP):
This submission includes a Predetermined Change Control Plan (PCCP) that defines the framework for implementing planned modifications to the CardIQ Suite software while ensuring continued safety, effectiveness, and substantial equivalence. The PCCP describes both the types of anticipated changes and the associated modification protocol, including verification, validation, and implementation processes. For each execution of change implemented under this PCCP, GE HealthCare will:

- Assign a unique software version identifier and maintain configuration management records for datasets, training configuration, and evaluation results.
- Document verification/validation outcomes, including predefined acceptance criteria results, as part of the design history records.

- Communicate changes to users through standard release mechanisms (e.g., release notes and labeling updates).

The PCCP covers two categories of changes, updates to existing AI models (heart segmentation, coronary segmentation, tracking/lumen segmentation, and coronary labeling) and Integration of PlaqID module ported over from reference device CardIQ Xpress 2.0 (K073138), without altering intended use or clinical outputs.
The PCCP does not introduce new or different questions of safety and effectiveness compared to the predicate device.
Table 2 describes each of the proposed modifications and corresponding testing method and performance criteria to ensure substantial equivalence of the device after the modification.

Table 2: PCCP Modification, Testing Method and Performance Criteria

Modification	Description	Testing Method	Performance Criteria
Heart Segmentation	Retraining with additional and more diverse datasets. These updates may include bounded refinements to model architecture, preprocessing/post-processing, training strategy, and optimization parameters, without altering intended use or clinical outputs	Dice Similarity Coefficient (DSC) – volumetric overlap (%)	**Algorithm level:** Success based on passing exams meeting predefined benchmark
Coronary Segmentation		DSC (Dice) and Geodesic Dice (DSC5) for surface-tolerant evaluation	**Algorithm level:** Success based on predefined benchmark
Coronary Tracking & Lumen Segmentation		Δd_min (minimum diameter difference) Mean Absolute Difference (MAD) of diameters	**Algorithm level:** Must meet benchmark
Coronary Labeling		Classification metrics: accuracy, precision, recall (per vessel and territory: RCA, LAD, LCX)	**Vessel level:** Correct anatomical territory assignment **Algorithm level:** Must meet benchmark
Integration of PlaqID Module	Addition of a rule-based functionality	CardIQ Suite PlaqID outputs	Agreement is defined as an

	ported over from reference device CardIQ Xpress 2.0. (K073138) to identify and quantify coronary plaque.	will be compared to those from the reference device using clinical datasets	absolute difference in HU-based plaque volume not exceeding predefined thresholds

Conclusion:

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

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. The PCCP will continue to ensure the safe and effectiveness of the product, and all modifications will maintain the device within stated intended use and indications for use.