March 11, 2022

GE Medical Systems SCS
% Yonghui Han
Regulatory Affairs Leader
283, rue de la Miniere
Buc, 78530
FRANCE

Re: K213725
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, LLZ
Dated: February 17, 2022
Received: February 18, 2022

Dear Yonghui Han:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Laurel Burk
Assistant Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K213725

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. Calcium Scoring may be used to monitor the progression/regression of calcium in coronary arteries overtime, which may aid in 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

K213725

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

Date:	November 23, 2021
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Yonghui Han Regulatory Affairs Leader GE Healthcare (86)10 57083350/(+86) 13311387032 Yonghui.Han@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:	CardIQ Suite
Primary Regulation Number: Primary Product Code: Secondary Product Code: Classification:	Computed Tomography X-Ray System (21 CFR 892.1750) JAK LLZ Class II

Predicate Device	
Device name:	SmartScore 4.0
Manufacturer:	GE Medical Systems SCS
510(k) number:	K020929
Regulation Number:	21 CFR 892.1750 Computed tomography X-Ray System
Product Code:	JAK
Classification:	Class II
Reference Devices	
Device name:	CardIQ Xpress 2.0
Manufacturer:	GE Medical Systems SCS
510(k) number:	K073138
Regulation Number:	21 CFR 892.1750 Computed tomography X-Ray System
Product Code:	JAK
Classification:	Class II
Device name:	Syngo.CT CaScoring
Manufacturer:	Siemens Medical Solutions USA, Inc.
510(k) number:	K201034
Regulation Number:	21 CFR 892.1750 Computed tomography X-Ray System
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.

CardIQ Suite provides the Coronary 2D Review toolset which allows interactive 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 such as chambers, valves and arteries in motion. 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. Calcium Scoring may be used to monitor the progression/regression of calcium in coronary arteries overtime, which may aid in the prognosis of cardiac disease.

Technology:

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

Comparison:

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

Specification	Predicate Device: SmartScore 4.0 (K020929)	Proposed Device: CardIQ Suite	Comparison
Segmentation and labeling calcific regions in the coronaries	Manual	Automated	**Substantial Equivalent** Deep Learning Algorithm is incorporated in CardIQ Suite to automatically segment and label the calcific regions in the coronary arteries in order to improve workflow efficiency over the manual approach that exists in the predicate device. Automated calcium scoring evaluation already exists in the reference device Syngo.CT CaScoring (K201034).
Manual Segmentation and labeling of calcific regions	Yes	Yes	**Identical**
Computation of Agatston score	Yes	Yes	**Identical**
Coronary 2D Review	Not Available	Yes	**Substantial Equivalent** Coronary 2D Reviews Toolset is available in CardIQ Suite to assist users for a seamless integrated review of coronary artery imaging along with automated calcium scoring feature. This tool set contains identical features to what already exists in the reference device CardIQ Xpress 2.0 (K073138)

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 (2016) 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 device. Software documentation is for a MODERATE level of concern.

In addition, Engineering has validated CardIQ Suite Calcium Scoring algorithm's capability to automatically segment, label and score the calcific regions in the coronary arteries 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

Three board certified radiologists manually scored a representative set of clinical sample images using the predicate device and the results were compared with the automated score outputted by CardIQ Suite. Very high correlations were found between manual and automated methods for computing the total calcium score, demonstrating equivalent performance of the CardIQ Suite software to the predicate device SmartScore 4.0.

Conclusion:

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

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 predicate.

Based on development under GE Healthcare's quality system, successful design verification, software documentation for a "Moderate" level of concern, along with the engineering bench testing and sample 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.