GE Medical Systems SCS
% Ms. Elizabeth Mathew
Senior Regulatory Affairs Manager
283 rue de la Miniere
Buc, 78530
FRANCE

February 14, 2020

Re: K192277
Trade/Device Name: CardIQ Flow
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS
Dated: January 14, 2020
Received: January 15, 2020

Dear Ms. Mathew:

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,

For

Thalia T. Mills, Ph.D.
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)*

K192277

Device Name

CardIQ Flow

Indications for Use *(Describe)*

CardIQ Flow is an aiding tool for the clinicians to perform analysis of sets of stationary, dynamic, or gated cardiac positron emission tomography (PET) images. The measurements include perfusion, end-diastolic & end-systolic volumes, stroke volume, ejection fraction, myocardial mass, and transient ischemic dilatation. Also included is a feature that enables clinicians to visualize reformatted data and make a comparison between stress and rest series. Software is indicated for determining regional and global absolute rest and stress myocardial perfusion in cc/min/g, Coronary Flow Reserve and their combination into the Coronary Flow Capacity (CFC) Map in patients with suspected or known coronary artery disease (CAD) in order to assist clinical interpretation of PET perfusion images by quantification of their severity. It is intended for use by trained professionals, such as nuclear technicians, nuclear medicine or nuclear cardiology physicians, or cardiologists with appropriate training. The clinician remains ultimately responsible for the final assessment and diagnosis based on standard practices, clinical judgment and interpretation of cardiac images or quantitative data.

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 K192277

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

Date:	August 21, 2019
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Elizabeth Mathew Senior Regulatory Affairs Manager GE Healthcare, (GE Medical Systems, LLC) 3000 N Grandview Blvd., Waukesha, WI - 53188 Phone: (262) 424-7774 Email: Elizabeth.Mathew@ge.com
Secondary Contact Person:	Helen Peng Sr. Regulatory Affairs Director GE Healthcare, (GE Medical Systems, LLC) 3000 N Grandview Blvd., Waukesha, WI - 53188 Phone: 262-424-8222 Email: Hong.Peng@ge.com
Proposed Device:	
Device Name:	CardIQ Flow
Common/Usual Name:	CardIQ Flow
Primary Regulation number: Primary Product Code:	21 CFR 892.1200 Emission computed tomography system KPS
Secondary Regulation number:	21 CFR 892.2050 Picture archiving and communications system
Secondary Product Code:	LLZ
Classification:	Class II

Primary Predicate Device:	
Device Name:	HeartSee
510(k) number:	K171303 cleared on September 22, 2017
Regulation number/ Product Code:	21 CFR 892.1200 Emission computed tomography system KPS
Classification:	Class II
Manufacturer:	University of Texas Medical School at Houston, Texas
Predicate Device:	
Device Name:	FullCard Analysis
510(k) number:	K061587 cleared on June 23rd, 2006
Regulation number/ Product Code:	21 CFR 892.1200 Emission computed tomography system KPS
Classification:	Class II
Manufacturer:	GE Healthcare

Device Description:

The basis for this submission is the introduction of a new software device, CardIQ Flow which integrates the functionalities of the predicate devices HeartSee and FullCard Analysis for the display and analysis of Cardiac PET images. It is built within the framework of the Volume Viewer (K041521) 3D platform, intended to aid clinicians in assessing the myocardium viability, myocardial perfusion, myocardial blood flow and wall motion. It is used for the evaluation of patients with known or suspected coronary artery or ischemic heart disease.

This application can be used for:
• Reformatting axial data to the standard axis of the heart. Axial data may have been reconstructed using iterative or FBP algorithms with scatter and attenuation correction, if available.
• Analyzing the myocardial perfusion by the Vertical Long Axis (VLA), Horizontal Long Axis (HLA) and Short Axis (SA) obliques generated from the selected input data.
• Comparing myocardial perfusion in rest and stress studies as well as metabolism in viability studies.
• Viewing wall motions via synchronized gated beating slices.
• Investigating the entire left ventricle in one 2D Polar Plot that displays all short axis slices.
• Comparing myocardial perfusion of corrected and uncorrected datasets.
• Calculation and evaluation of Myocardial Blood Flow (MBF), Coronary Flow Reserve (CFR), and Coronary Flow Capacity (CFC).
• Printing a report designed for referring physicians.

Intended use:

CardIQ Flow is a fully integrated post-processing and analysis tool tailored for PET cardiac imaging. CardIQ Flow is designed to provide an easy-to-use and efficient tool aiding clinical interpretation for patients with suspected or known coronary artery disease (CAD) with quantification of their severity.

Indications for use:

CardIQ Flow is an aiding tool for the clinicians to perform analysis of sets of stationary, dynamic, or gated cardiac positron emission tomography (PET) images. The measurements include perfusion, end-diastolic & end-systolic volumes, stroke volume, ejection fraction, myocardial mass, and transient ischemic dilatation. Also included is a feature that enables clinicians to visualize reformatted data and make a comparison between stress and rest series. Software is indicated for determining regional and global absolute rest and stress myocardial perfusion in cc/min/g, Coronary Flow Reserve and their combination into the Coronary Flow Capacity (CFC) Map in patients with suspected or known coronary artery disease (CAD) in order to assist clinical interpretation of PET perfusion images by quantification of their severity. It is intended for use by trained professionals, such as nuclear technicians, nuclear medicine or nuclear cardiology physicians, or cardiologists with appropriate training. The clinician remains ultimately responsible for the final assessment and diagnosis based on standard practices, clinical judgment and interpretation of cardiac images or quantitative data.

Technological Characteristic:

CardIQ Flow employs the same technologies as those of the Predicates.

HeartSee (K171303) is a software tool for cardiac positron emission tomography (PET) for determining regional and global absolute rest and stress myocardial perfusion in cc/min/g, Coronary Flow Reserve and their combination into the Coronary Flow Capacity (CFC) Map for facilitating the interpretation of PET perfusion images in patients with suspected of known coronary artery disease.

FullCard Analysis (K061587) is a post processing analysis software package designed to provide a totally integrated package including automated processing, visualization, quantification of parameters of myocardial perfusion and function, along with simple reporting capabilities. The parameters include perfusion, end-diastolic & end-systolic volumes, stroke volume, ejection fraction, myocardial mass, and transient ischemic dilatation.

CardIQ Flow is a software which integrates together the functionalities from HeartSee and FullCard Analysis in order to be able to display and analyze Cardiac PET images. CardIQ Flow when compared to HeartSee has the same workflow leading to the computation of the CFC (ROI Deposition, blood flow and CFR computation). CardIQ Flow has based the computation of the different maps on HeartSee's **2D** formulas, but has tuned them to **3D** in order to augment the clinical review capabilities. Similar to HeartSee, the segmentation in CardIQ Flow can be

manually adjusted using dedicated tools so that the user can control where blood flow will be computed.

CardIQ Flow has the same workflow as FullCard Analysis and has incorporated the same formulas as FullCard Analysis to quantify the parameters (perfusion, end-diastolic & end-systolic volumes, stroke volume, ejection fraction, myocardial mass, and transient ischemic dilatation) of myocardial perfusion and function.

As CardIQ Flow is built within Volume Viewer, CardIQ Flow inherits the below existing capabilities from Volume Viewer:
- Display of the maps
- Display of the statistics
- Display of the CFC graph
- ROI deposition
- Report of the maps and statistics

Comparison

The table below summarizes the feature/technological comparison between the predicate device and the proposed device:

Specification	**Primary Predicate: HeartSee (K171303)**	**Predicate Device: FullCard Analysis (K061587)**	**Proposed Device: CardIQ Flow**	**Comparison**
Workflow for computation of Coronary Flow Capacity (CFC)	ROI Deposition, Blood Flow and Coronary Flow Reserve (CFR) computation	NA	ROI Deposition, Blood Flow and Coronary Flow Reserve (CFR) computation	Proposed device is substantially equivalent to the Primary Predicate Device - HeartSee
Myocardium Identification	HeartSee uses a 2D box to define the myocardium.	Automatic 3D Myocardium Segmentation algorithm.	Automatic 3D Myocardium Segmentation algorithm.	Substantial Equivalent to the predicate devices.
Map Output	2D maps Rendering	NA	3D maps Rendering	Substantial Equivalent to the Primary Predicate Device – HeartSee.
Measurements	NA	The measurements include perfusion, end-diastolic & end-systolic volumes, stroke	The measurements include perfusion, end-diastolic & end-systolic volumes, stroke	Identical to Predicate Device – FullCard Analysis

		volume, ejection fraction, myocardial mass, and transient ischemic dilatation.	volume, ejection fraction, myocardial mass, and transient ischemic dilatation.	

Determination of Substantial Equivalence:

CardIQ Flow has successfully completed the required design control activities per GE's quality management system that complies to Quality System Regulations of 21CFR 820 and ISO 13485 The following quality assurance measures have been applied to the development of the device:

- Risk Analysis and Mitigation
- Requirements Reviews
- Design Reviews
- Performance testing (Verification, Validation)
- Safety testing (Verification)

The testing and results did not raise new questions of safety and effectiveness from those associated with predicate devices and demonstrated that the CardIQ Flow performs subdistally equivalent to the predicate devices.

The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Conclusion
GE Healthcare considers CardIQ Flow to be as safe, as effective as the predicate devices, and is substantially equivalent to the predicate devices.