November 22, 2022

GE Medical Systems SCS
℅ Tong Zhao
Regulatory Affairs Leader
283, rue de la Miniere
Buc, 78530
FRANCE

Re: K222895
Trade/Device Name: DynamicIQ
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, LLZ
Dated: September 21, 2022
Received: September 23, 2022

Dear Tong Zhao:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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)*

K222895

Device Name

DynamicIQ

Indications for Use *(Describe)*

DynamicIQ enables visualization and quantification of PET tracer pharmacokinetics based on whole body dynamic PET images. PET tracer pharmacokinetics include the physiological parameters of tracer uptake rate (Ki), metabolic rate of the tracer and total blood distribution volume (Vd) that allow for analyzing and visualizing the tracer accumulation over time, providing additional information that may help in the evaluation of SUV measurements on PET static images. The output of DynamicIQ is intended to be used by appropriately trained healthcare professionals as adjunct information for the review, analysis, and communication of PET static images for diagnosis, staging, treatment planning and monitoring. The parametric images should always be considered in addition to the conventional static PET images, which are the primary source to assist with diagnosis.

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

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

Date:	September 21, 2022
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Tong Zhao Regulatory Affairs Leader GE Healthcare (+86) 15142077290 Email: Tong.Zhao2@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:	DynamicIQ
Common/Usual Name:	DynamicIQ
Primary Regulation Number: Primary Product Code: Secondary Product Code: Classification:	Emission computed tomography system (21 CFR 892.1200) KPS LLZ Class II

Predicate Device	
Device name:	Biograph Horizon PET/CT
Manufacturer:	Siemens Medical Solutions USA, Inc.
510(k) number:	K193178
Regulation Number:	21 CFR 892.1200 Emission computed tomography system
	21 CFR 892.1750 Computed Tomography X-Ray System
Product Code:	KPS, JAK
Classification:	Class II
Reference Devices	
Device name:	PET VCAR
Manufacturer:	GE Medical Systems SCS
510(k) number:	K211247
Regulation Number:	21 CFR 892.1200 Emission computed tomography system
	21 CFR 892.2050 Medical image management and processing system
Product Code:	KPS, LLZ
Classification:	Class II

Device Description:

DynamicIQ is a post processing and visualization application for visualizing and quantifying dynamic and static PET DICOM series. The software provides FDG tracer pharmacokinetics by generation of parametric images based on dynamic PET scans. The parametric images include physiological parameters of tracer uptake rate (Ki), metabolic rate of FDG and total blood distribution volume (Vd). In addition to the FDG Tracer pharmacokinetics, the software also performs the conventional review, analysis and communication of conventional PET static images, CT and MR images.

DynamicIQ assists with the clinical workflow by providing adjunct information of FDG tracer pharmacokinetics along with conventional PET static images and CT/MR images for cross reference. The adjunct information of FDG tracer pharmacokinetics also help with analyzing the images that could have variability of quantitative measurements due to differences in uptake time, patient body size and blood glucose levels, leading to better characterization of tracer uptake compared to SUV alone.

Intended Use:

DynamicIQ enables visualization and quantification of PET tracer pharmacokinetics based on whole body dynamic PET images. The output of DynamicIQ is intended to be used by appropriately trained healthcare professionals as adjunct information for the review, analysis, and communication of conventional static PET images for diagnosis, staging, treatment planning and monitoring.

Indication for Use:

DynamicIQ enables visualization and quantification of PET tracer pharmacokinetics based on whole body dynamic PET images. PET tracer pharmacokinetics include the physiological parameters of tracer uptake rate (Ki), metabolic rate of the tracer and total blood distribution volume (Vd) that allow for analyzing and visualizing the tracer accumulation over time, providing additional information that may help in the evaluation of SUV measurements on PET static images. The output of DynamicIQ is intended to be used by appropriately trained healthcare professionals as adjunct information for the review, analysis, and communication of PET static images for diagnosis, staging, treatment planning and monitoring. The parametric images should always be considered in addition to the conventional static PET images, which are the primary source to assist with diagnosis.

Technology:

The proposed device DynamicIQ 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:

Note: Proposed device DynamicIQ compares with “FlowMotion Multi - Parametric PET AI” which is a feature of Siemens Biograph Horizon PET/CT system (K193178). Other features of the predicate device are outside of the scope of the comparison.

Specification	**Predicate Device: Biograph Horizon PET/CT (K193178)**	**Proposed Device: DynamicIQ**	**Comparison**
Location of Processing	During scanning	Post-processing	**Substantially Equivalent**
Estimation of input function from blood pool scan	Yes	Yes	**Substantially Equivalent** Both predicate and proposed device generate tracer Time Activity Curve (TAC) from blood pool scan

Estimation of input function without blood pool scan	Yes	Yes	**Substantially Equivalent** Predicate and proposed device manage missing input function case in different manners: Predicate uses manually inputted values while proposed device uses Relative Patlak Analysis.
Output (Absolute Patlak Analysis)	Yes	Yes	**Identical.** Generation of parametric images using Patlak model (Ki, Vd, Metabolic rate of FDG).
Output (Relative Patlak analysis)	Not applicable	Yes	**Substantially Equivalent** Proposed device has Relative Patlak analysis mode to deliver Relative tracer uptake rate Ki which has been shown to lead to visually identical images to the Absolute Patlak analysis. Quantitative values are not available and Vd is not available.
Result Review	Yes	Yes	**Substantially Equivalent** Both applications can display static and dynamic PET images, CT and MR images (if available). Both applications include an interactive toolset to delineate findings and extract measurements from the static and dynamic PET images.

DynamicIQ is substantially equivalent to FlowMotion Multiparametric PET AI of Biograph Horizon PET/CT. The main differences between the proposed device and predicate device are:

- The proposed device is a standalone image post-processing software while the predicate is embedded into the Biograph Horizon PET/CT system.
- The proposed device performs a Relative Patlak analysis when a blood pool scan is not available as input, while the predicate requires a manual radiation titration to be entered to conduct the Patlak Analysis. The Relative Patlak analysis has been shown to lead to visually identical images to the Absolute Patlak analysis.

These differences do not raise new type of safety and effectiveness questions.

Determination of Substantial Equivalence:

Summary of Non-Clinical, Design Control Testing

DynamicIQ 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 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 DynamicIQ has been successfully verified on the AW VolumeShare workstation and AW Server platforms. Software documentation is for a MODERATE level of concern.

Conclusion:

DynamicIQ has substantial equivalent technological characteristics as its predicate device.

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, GE Healthcare believes that the proposed DynamicIQ is substantially equivalent to, and hence as safe and as effective for its Intended Use as the legally marketed predicate device.