GE Medical Systems SCS   July 27, 2021
℅ Ms. Elizabeth Mathew
Senior Regulatory Affairs Manager
283, rue de la Miniere
Buc, 78530
FRANCE

Re: K211247
    Trade/Device Name: PET VCAR
    Regulation Number: 21 CFR 892.1200
    Regulation Name: Emission computed tomography system
    Regulatory Class: Class II
    Product Code: KPS, LLZ
    Dated: July 12, 2021
    Received: July 13, 2021

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

Indications for Use

510(k) Number *(if known)*

K211247

Device Name

PET VCAR

Indications for Use *(Describe)*

PET VCAR (Volume Computer Assisted Reading) is a PET/CT software package which can be used by the clinician to assist in diagnosis, staging, treatment planning and monitoring treatment response. PET VCAR automatically highlights and bookmarks PET defined regions of interest based on user-defined threshold settings. The software can be used for visualization and analytical monitoring of disease progression or response to treatment or therapy using multi exam comparison. The software is designed to measure Standard Uptake Value (SUV) and volume for any PET defined metabolic activity. The software automatically propagates bookmarks from one time point to another for the purpose of improving analysis and workflow, which is designed to allow clinicians to make informed follow-up decisions in an efficient manner. PET VCAR does not provide or claim any automatic detection or automatic diagnosis of abnormal anatomy, structure or function.

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.

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided.　　K211247

Date:	July 22, 2021
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283, rue de la Minière 78530 Buc, France
Primary Contact:	Elizabeth Mathew Senior Regulatory Affairs Manager GE Healthcare Tel: (262)424-7774 Email: Elizabeth.Mathew@ge.com
Secondary Contact	Helen Peng Senior Regulatory Affairs Director Tel: (262)424-8222 Email: Hong.Peng@ge.com
Device Trade Name: Common/Usual Name: Primary Regulation Number: Primary Product Code: Secondary Product Code: Classification:	**PET VCAR** PET VCAR 21 CFR 892.1200 Emission computed tomography system KPS LLZ Class II
Predicate Device: Device Name: Manufacturer: 510(k) number: Regulation Number: Product Code: Classification:	 PET VCAR GE Medical Systems SCS K063324 21 CFR 892.1750 Computed tomography X-Ray system 21 CFR 892.1200 Emission computed tomography system JAK KPS Class II

Device Description and Marketed Devices:

PET VCAR (Volume Computer Assisted Reading) is a PET/CT post processing software package which can be used by the trained clinician to assist in diagnosis, staging, treatment planning and monitoring treatment response. PET VCAR automatically highlights and bookmarks PET defined regions of interest based on user defined threshold settings. Bookmarks are any highlighted item including 2D or 3D region of interests and their associated measurements and annotations on the images. The software can be used for visualization and analytical monitoring of disease progression or response to treatment or therapy using multi exam comparison. It is designed to measure PET Standard Uptake Value (SUV) and volume for any PET defined metabolic activity. The software automatically propagates bookmarks from one time point to another for the purpose of improving analysis and workflow. Bookmark propagating is the feature that allows all bookmarks from the baseline exam of the patient to be automatically populated to subsequent exams of the same patient to facilitate the analysis of changes between the exams.

PET VCAR offers a tool called Summary Table that compiles and manages all the analytical information in an organized and interactive design. The Summary Table is synchronized with the image display layouts offering quick measurement / image visual validation. PET VCAR's workflow is designed to allow clinicians to make informed follow-up decisions in an efficient manner. PET VCAR does not provide or claim any automatic detection or automatic diagnosis of abnormal anatomy, structure, or function.

Intended Use:

PET VCAR (Volume Computer Assisted Reading) is a PET/CT software package which can be used by the clinician to assist in diagnosis, staging, treatment planning and monitoring treatment response.

Indication for Use:

PET VCAR (Volume Computer Assisted Reading) is a PET/CT software package which can be used by the clinician to assist in diagnosis, staging, treatment planning and monitoring treatment response. PET VCAR automatically highlights and bookmarks PET defined regions of interest based on user-defined threshold settings. The software can be used for visualization and analytical monitoring of disease progression or response to treatment or therapy using multi exam comparison. The software is designed to measure Standard Uptake Value (SUV) and volume for any PET defined metabolic activity. The software automatically propagates bookmarks from one time point to another for the purpose of improving analysis and workflow, which is designed to allow clinicians to make informed follow-up decisions in an efficient manner. PET VCAR does not provide or claim any automatic detection or automatic diagnosis of abnormal anatomy, structure or function.

Technology:

The proposed device PET VCAR employs the same fundamental scientific technology as its predicate device.

Comparison:

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

Specification	Predicate Device: PET VCAR (K063324)	Proposed Device: PET VCAR	Comparison
Indications for Use	PET VCAR (Volume Computer Assisted Reading) is a PET/CT software package which can be used by the clinician to assist in diagnosis, staging, treatment planning and monitoring treatment response. PET VCAR automatically highlights and bookmarks PET defined regions of interest based on user-defined threshold settings. The software can be used for visualization and analytical monitoring of disease progression or response to treatment or therapy using multi exam comparison. The software is designed to measure Standard Uptake Value (SUV) and volume for any PET defined metabolic activity. The software automatically propagates bookmarks from one time point to another for the purpose of	PET VCAR (Volume Computer Assisted Reading) is a PET/CT software package which can be used by the clinician to assist in diagnosis, staging, treatment planning and monitoring treatment response. PET VCAR automatically highlights and bookmarks PET defined regions of interest based on user-defined threshold settings. The software can be used for visualization and analytical monitoring of disease progression or response to treatment or therapy using multi exam comparison. The software is designed to measure Standard Uptake Value (SUV) and volume for any PET defined metabolic activity. The software automatically propagates bookmarks from one time point to another for the purpose of	Substantially Equivalent. The Proposed Device's Indications for Use is simplified by removing the underlined text from those of the predicate. We also changed the name of "Interactive Data Analysis (IDA) spreadsheet "to the "summary table". These minor changes do not change the clinical meaning of the indications and are made for improved clarity and simplicity.

Specification	Predicate Device: PET VCAR (K063324)	Proposed Device: PET VCAR	Comparison
	improving analysis and workflow. <u>PET VCAR offers a tool called Interactive Data Analysis (IDA) spreadsheet that compiles and manages all the analytical information in an organized and interactive design. The IDA is synchronized with the image display layouts offering quick measurement / image visual validation.</u> PET VCAR's workflow is designed to allow clinicians to make informed follow-up decisions in an efficient manner. PET VCAR does not provide or claim any automatic detection or automatic diagnosis of abnormal anatomy, structure or function.	improving analysis and workflow, which is designed to allow clinicians to make informed follow-up decisions in an efficient manner. PET VCAR does not provide or claim any automatic detection or automatic diagnosis of abnormal anatomy, structure or function.	
PET lesion Segmentation	Yes	Yes	Substantially Equivalent The subject device additionally provides user flexibility to manually edit the bookmarks if desired.
Automatic VOI placement in the liver	Not Available	Yes	Substantially Equivalent Subject device places an initial VOI in the liver for user convenience.
Deauville Score	Not Available	Yes	Substantially Equivalent Subject device implements Deauville Score

Specification	Predicate Device: PET VCAR (K063324)	Proposed Device: PET VCAR	Comparison
PERCIST	Not Available	Yes	Substantially equivalent Subject device implements PERCIST evaluation Criteria
EORTC	Yes (customer defined threshold)	Yes (automated)	Substantially Equivalent
Bone lesion identification and lesion extent calculation	Manual bone segmentation & PET Lesion Segmentation	Automated Bone Segmentation & PET Lesion Segmentation	Substantially Equivalent

Determination of Substantial Equivalence:

Summary of Non-Clinical, Design Control Testing

PET VCAR 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)

In addition, bench testing was performed to evaluate the performance of the automatic reference region VOI placement algorithm and the algorithm passed the defined acceptance criteria.

The proposed PET VCAR has been successfully verified on the AW VolumeShare workstation and AW Server platforms. 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 for a MODERATE level of concern.

Substantial Equivalence Conclusion:

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