GE Medical Systems SCS
% Ms. Helen Peng
Director, Regulatory Affairs Leader, MICT & AW
GE Medical Systems, LLC
3000 North Grandview Blvd.
WAUKESHA WI 53188

March 29, 2019

Re: K183210
Trade/Device Name: Thoracic VCAR with GSI Pulmonary Perfusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, JAK
Dated: March 19, 2019
Received: March 20, 2019

Dear Ms. Peng:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K183210

Device Name

Thoracic VCAR with GSI Pulmonary Perfusion

Indications for Use *(Describe)*

Thoracic VCAR is a CT, non-invasive image analysis software package, which may be used in conjunction with CT lung images to aid in the assessment of thoracic disease. The software provides automatic segmentation of the lungs and automatic segmentation and tracking of the airway tree. Thoracic VCAR also provides quantification of Hounsfield units and display by color of thresholds within a segmented region.

Thoracic VCAR also supports Gemstone Spectral Imaging (GSI) acquisitions for the evaluation of pulmonary perfusion. It provides additional information to aid in visualization of variations of perfusion within the lungs and to quantitatively assess lung volumes. It is intended to be used as an adjunct to current standard methods utilizing color coded displays of iodine attenuation differences in the lungs to aid in identifying segments of relative perfusion differences which may be useful in assessing thoracic disease. Thoracic diseases that may be associated with changes in perfusion include pulmonary embolism and COPD.

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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K183210

510(k) Summary

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

Date:	November 16, 2018
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283, rue de la Minière 78530 Buc, France
Primary Contact Person:	Peter Uhlir Regulatory Affairs Leader Tel: 00 36 1 4793318 Email: Peter.Uhlir@ge.com
Secondary Contact Person:	Helen Peng Director, Regulatory Affairs Leader, MICT & AW Tel: (262) 424-8222 Email: Hong.Peng@ge.com
Device Trade Name:	Thoracic VCAR with GSI Pulmonary Perfusion
Common/Usual Name:	Thoracic VCAR
Proposed Device: Primary Regulation Number/ Primary Product Code: Secondary Product Code: Classification Panel: Regulatory Class:	 21CFR 892.2050, Picture archiving and communications System/LLZ JAK Radiology Class II
Predicate Device: 510(k) number Regulation Number/ Product Code: Classification Panel: Regulatory Class: Manufacturer:	Thoracic VCAR K103480, cleared on March 7, 2011 21CFR 892.2050, Picture archiving and communications system/LLZ Radiology Class II GE Healthcare (GE Medical Systems LLC)

Device Description:	Thoracic VCAR is a software analysis package for the Advantage Workstation (AW) platform, CT Scanner, Cloud or PACS stations which can be used in the analysis of CT images. It is designed for the analysis and processing of volumetric CT chest data. It provides quantitative information to aid in the assessment of thoracic diseases. The primary features of the software are: lung and lobe segmentation to obtain threshold-based volume measurements; bronchial tree segmentation and tracking to determine wall thickness measurements; lung maps based on HU values to help the physician in determining the location and extent of disease across both lungs a well as each lobe. Additionally, GSI datasets can be used for the evaluation of relative perfusion within the lungs.
Intended Use:	Thoracic VCAR is a CT, non-invasive image analysis software package, which may be used in conjunction with CT lung images to aid in the assessment of thoracic disease diagnosis and management.
Indications for Use:	Thoracic VCAR is a CT, non-invasive image analysis software package, which may be used in conjunction with CT lung images to aid in the assessment of thoracic disease. The software will provide automatic segmentation of the lungs and automatic segmentation and tracking of the airway tree. The software will provide quantification of Hounsfield units and display by color the thresholds within a segmented region. Thoracic VCAR also supports Gemstone Spectral Imaging (GSI) acquisitions for the evaluation of pulmonary perfusion. It provides additional information to aid in visualization of variations of perfusion within the lungs and to quantitatively assess lung volumes. It is intended to be used as an adjunct to current standard methods utilizing color coded displays of iodine attenuation differences in the lungs to aid in identifying segments of relative perfusion differences which may be useful in assessing thoracic disease. Thoracic diseases that may be associated with changes in perfusion include pulmonary embolism and COPD.
Technology:	The Thoracic VCAR with GSI Pulmonary Perfusion software employs the same fundamental scientific technology as its predicate device. The GSI Pulmonary Perfusion protocol relies on the predicate device's capability to provide tools to review thoracic datasets. It uses the lungs and lung vessels segmentation already present in

	Thoracic VCAR, applied to GSI datasets and combines the segmentation to GSI material density (MD) images.

Comparison:

The most notable change in Thoracic VCAR with GSI Pulmonary Perfusion as compared to Thoracic VCAR is that it allows to use GSI datasets for the evaluation of relative perfusion within the lungs.

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

Specification	**Predicate Device Thoracic VCAR (K103480)**	**Proposed Thoracic VCAR with GSI Pulmonary Perfusion**
Modality images supported	CT chest dataset	Same + GSI CT chest dataset
Automatic lungs, Lobe, Airway tree segmentation	Yes	Yes
Manual editing of segmentation results	Yes	Yes
Relative perfusion deficit map in the lung parenchyma regions with GSI Pulmonary Perfusion protocol	No	Yes
Summary Table automatically displays total volume of segmented lungs as well as relative hypo-perfusion volumes	No	Yes

Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: Engineering has validated the algorithm for Thoracic VCAR with GSI Pulmonary Perfusion in order to prove the capabilities of the algorithm for the evaluation of relative perfusion within the lungs. In order to demonstrate the effectiveness of the algorithm in identifying and separating the iodine(water) distributions within the lungs we designed a phantom test with a test setup that simulates regions of relative perfused and non-perfused volumes inside of a commercially available anthropomorphic lung phantom. This simulated bench testing demonstrates that the algorithm correctly segmented/thresholded the modeled lung regions that had relative perfusion differences (Iodine concentrations). The Thoracic VCAR with GSI Pulmonary Perfusion software complies with NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard. Thoracic VCAR with GSI Pulmonary Perfusion has successfully completed the required design control testing per GE's quality system. Thoracic VCAR with GSI Pulmonary Perfusion was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system: ▪ Risk Analysis ▪ Requirements Reviews ▪ Design Reviews ▪ Performance testing (Verification, validation) ▪ Safety testing (Verification) The substantial equivalence determination is also based on the software documentation for a MODERATE level of concern device. Summary of Clinical tests: A representative clinical sample image set of 15 CT cases were assessed by three board certified radiologists using 5 point Likert scale. This data is representative of routine clinical imaging from thoracic acquisition perspective, in which such a tool is most likely to be utilized. The assessment demonstrated the proposed device improves diagnostic value, reader confidence and efficiency in evaluating relative distribution of iodine within the lungs such as in the presence of pulmonary emboli.
Conclusion:	GE Healthcare considers the Thoracic VCAR with GSI Pulmonary Perfusion software application to be as safe, as effective, and performance is substantially equivalent to the predicate device.