GE Medical Systems SCS
% Lifeng Wang
Regulatory Affairs Manager
283 rue de la Miniere
78530 Buc
FRANCE

March 20, 2020

Re: K193281
Trade/Device Name: Hepatic VCAR
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray System
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: February 19, 2020
Received: February 20, 2020

Dear Lifeng Wang:

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 and Part 809); 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)*

K193281

Device Name

Hepatic VCAR

Indications for Use *(Describe)*

Hepatic VCAR is a CT image analysis software package that allows the analysis and visualization of Liver CT data derived from DICOM 3.0 compliant CT scans. Hepatic VCAR is designed for the purpose of assessing liver morphology, including liver lesion, provided the lesion has different CT appearance from surrounding liver tissue; and its change over time through automated tools for liver, liver lobe, liver segments and liver lesion segmentation and measurement. It is intended for use by clinicians to process, review, archive, print and distribute liver CT studies.

This software will assist the user by providing initial 3D segmentation, vessel analysis, visualization, and quantitative analysis of liver anatomy. The user has the ability to adjust the contour and confirm the final segmentation.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K193281

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

Date:	Nov 26, 2019
Submitter:	GE Medical Systems SCS (Establishment Registration Number – 9611343) 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Lifeng Wang Regulatory Affairs Manager GE Healthcare Phone: +86 10 57083145 Email: lifeng.wang@ge.com
Secondary Contact Person:	Elizabeth Mathew Senior Regulatory Affairs Manager GE Healthcare Phone: (262) 424-7774 Email: Elizabeth.Mathew@ge.com
Proposed Device	➢ Device Name: Hepatic VCAR ➢ Regulation number/ Product Code: 21 CFR 892.1750 Computed tomography x-ray system / JAK ➢ Secondary Regulation number/ Product Code: 21 CFR 892.2050 Picture archiving and communications system/ LLZ ➢ Classification: Class II
Predicate Device:	➢ Device Name: Hepatic VCAR ➢ 510(k) number: K133649 ➢ Regulation number/ Product Code: 21 CFR 892.1750 Computed tomography x-ray system / JAK ➢ Secondary Regulation number/ Product Code: 21 CFR 892.2050 Picture archiving and communications system/ LLZ ➢ Classification: Class II
Device Description	Hepatic VCAR is a CT image analysis software package that allows the analysis and visualization of Liver CT data derived from DICOM 3.0 compliant CT scans. Hepatic VCAR was designed for the purpose of assessing liver morphology, including liver lesion, provided the lesion has different CT appearance from surrounding liver tissue; and its change over time through automated tools for liver, liver lobe, liver segments and liver lesion segmentation and measurement. Hepatic VCAR is a post processing software medical device built on the Volume Viewer (K041521) platform, and can be deployed on the Advantage Workstation

<table>
<tr><td></td><td>(AW) (K110834) and AW Server (K081985) platforms, CT Scanners, and PACS stations or cloud in the future.

This software will assist the user by providing initial 3D segmentation, vessel analysis, visualization, and quantitative analysis of liver anatomy. The user has the ability to adjust the contour and confirm the final segmentation.

In the proposed device, two new algorithms utilizing deep learning technology were introduced. One such algorithm segments the liver producing a liver contour editable by the user; another algorithm segments the hepatic artery based on an initial user input point. The hepatic artery segmentation is also editable by the user.</td></tr>
<tr><td>Intended Use/ Indication for Use:</td><td>Hepatic VCAR is a CT image analysis software package that allows the analysis and visualization of Liver CT data derived from DICOM 3.0 compliant CT scans. Hepatic VCAR is designed for the purpose of assessing liver morphology, including liver lesion, provided the lesion has different CT appearance from surrounding liver tissue; and its change over time through automated tools for liver, liver lobe, liver segments and liver lesion segmentation and measurement. It is intended for use by clinicians to process, review, archive, print and distribute liver CT studies.

This software will assist the user by providing initial 3D segmentation, vessel analysis, visualization, and quantitative analysis of liver anatomy. The user has the ability to adjust the contour and confirm the final segmentation.</td></tr>
<tr><td>Technology:</td><td>The modified Hepatic VCAR employs two deep learning convolutional neural networks to segment the liver contour and the hepatic artery on CT liver exams while the predicate device uses a traditional deterministic method to segment the liver and manual tools to segment the vascular structure including the hepatic artery. These changes do not change the Indications for Use from the predicate, and represent equivalent technological characteristics, with no impact on control mechanism, and operating principle.

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

<table>
<tr><th>Specification</th><th>Predicate Device: Hepatic VCAR (K133649)</th><th>Proposed Device: Hepatic VCAR</th></tr>
<tr><td>Liver segmentation</td><td>Atlas algorithm based segmentation</td><td>Deep Learning algorithm based segmentation</td></tr>
<tr><td>Hepatic artery segmentation</td><td>Manual segmentation tools (“autoselect” and scalpel)</td><td>Semi-automatic segmentation workflow based on deep learning segmentation of the hepatic artery and edition</td></tr>
</table>
</td></tr>
</table>

				tools to correct/refine the result.
Determination of Substantial Equivalence:	Verification and validation including risk mitigations have been executed with results demonstrating Hepatic VCAR met the design inputs and user needs with no unexpected results or risks. Hepatic VCAR was designed and will be manufactured under the 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 • Requirements Reviews • Design Reviews • Performance testing (Verification, Validation) • Safety testing (Verification) Bench tests that compare the output of the two new algorithms with ground truth annotated by qualified experts show that the algorithms performed as expected. A representative set of clinical sample images was assessed by 3 board certified radiologists using 5-point Likert scale. The assessment demonstrated that capability of liver segmentation and hepatic artery segmentation utilizing the deep learning algorithm by Hepatic VCAR. The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.			
Conclusion:	GE Healthcare considers proposed device Hepatic VCAR to be as safe, as effective, and performance is substantially equivalent to the predicate device.			