K133649

APR 2 2 2014

510(k) Summary

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

Date:	November 25, 2013
Submitter:	GE Medical Systems SCS 283, rue de la Minière 78530 Buc, France
Primary Contact Person:	Peter Uhlir Regulatory Affairs Leader Tel: 00 36 23 410121 Fax: (262) 364 2506
Secondary Contact Person:	Huy Doan Regulatory Affairs Director GE Healthcare Tel: (414) 581-8553 Fax: (262) 364 2506
Device Trade Name:	Hepatic VCAR
Common/Usual Name:	Hepatic VCAR
Classification Names: Product Code:	21CFR 892.1750, Radiology JAK
Predicate Device(s):	K041521 - Volume Viewer Plus
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 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. 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. Key functionalities of the Hepatic VCAR include: a. Lesion segmentation

	b. Liver segmentation c. Portal vein segmentation d. Segment Separation by Portal Vein Branches e. Virtual Scalpel feature Hepatic VCAR is also made available as a standalone post processing application on the AW VolumeShare 5 workstation and the AW Server image processing platforms that host advanced image processing applications.

Indications for Use / Intended Use:	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.
Technology:	The Hepatic VCAR software employs the same fundamental scientific technology as its predicate device.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The Hepatic VCAR software complies with NEMA PS 3.1 - 3.20 (2011) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard. The Hepatic VCAR software employs the same fundamental scientific technology as its predicate device (Volume Viewer). Hepatic VCAR SW uses the equivalent CT DICOM image data input requirements. It has equivalent display, formatting, archiving and visualization technologies compared to the predicate device. Hepatic VCAR utilizes the enhanced segmentation tools (threshold, auto-select) already found in Volume Viewer and optimizes the segmentation algorithms for lesion segmentation, liver segmentation, vessel (Portal Vein) segmentation and liver lobe segmentation. The Virtual Scalpel feature takes advantage of the existing enhanced visualization capabilities and provides for an alternative way to virtually separate liver partitions, independently of portal vein segmentation. Thorough testing of these capabilities has not raised any safety or effectiveness issues.

	The following quality assurance measures were applied to the development of the system: ▪ Risk Analysis ▪ Requirements Reviews ▪ Design Reviews ▪ Integration testing (System verification) ▪ Performance testing (Bench testing, verification) ▪ Safety testing (Verification) The substantial equivalence determination is based on the software documentation for a MODERATE level of concern device.
Conclusion:	GE Healthcare considers the Hepatic VCAR software application to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 22, 2014

GE Medical Systems SCS
Huy Doan
Director, Global Regulatory Affairs
3000 N. Grandview
WAUKESHA WI 53188

Re: K133649
Trade/Device Name: Hepatic VCAR
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 21, 2014
Received: March 24, 2014

Dear Mr. Doan:

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. 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.

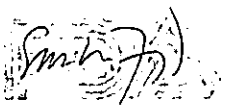
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K133649

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.
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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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