



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Ge Medical Systems SCS
% Jeme Wallace
Regulatory Affairs Director
GE Healthcare
540 W Northwest Highway
BARRINGTON IL 60010

January 20, 2016

Re: K152584
Trade/Device Name: Stroke VCAR
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: December 17, 2015
Received: September 18, 2015

Dear Jeme Wallace:

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” (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 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned above the printed name and title.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152584

Device Name
Stroke VCAR

Indications for Use (Describe)

Stroke VCAR is a CT image analysis software package that provides information to physicians to assist them in the analysis and visualization of Brain CT data derived from DICOM 3.0 compliant CT scans. Stroke VCAR is designed for the purpose of segmenting and assessing intracerebral and intracranial hemorrhages in the brain using semi-automated tools on non-contrast CT exams. Additionally Stroke VCAR provides a set of workflow tools for the segmentation and visualization of aneurysms in the brain from contrast enhanced CT exams. It is intended for use by clinicians to process, review, archive, print and distribute CT studies.

This software will assist the user by providing initial 3D segmentation, measurements and visualization of hemorrhages and aneurysm in the brain. The user has the ability to adjust, review and has to 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.

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510(k) Summary

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

Date:	September 9, 2015
Submitter:	GE Medical Systems SCS 283, rue de la Minière 78530 Buc, France
Primary Contact Person:	Peter Uhler Regulatory Affairs Leader Tel: 00 36 1 4793318 Fax: (847) 277 5240
Secondary Contact Person:	Jeme Wallace Regulatory Affairs Director GE Healthcare Tel: (847) 277 4468 Fax: (847) 277 5240
Device Trade Name:	Stroke VCAR
Common/Usual Name:	Stroke VCAR
Classification Names: Product Code:	21CFR 892.1750, Radiology JAK
Predicate Device(s):	K041521 - Volume Viewer Plus
Device Description / Intended Use:	Stroke VCAR is intended to provide 2D and 3D processing, review and analysis of CT images originally acquired to evaluate the cerebral vascular system and/or intracranial bleeding. The combination of the acquired images, reconstructed images, and measurements performed by the clinician using Stroke VCAR are intended to provide the referring physician clinically relevant information for the purpose of diagnosis, treatment planning and follow-up.



<p>Indications for Use:</p>	<p>Stroke VCAR is a CT image analysis software package that provides information to physicians to assist them in the analysis and visualization of Brain CT data derived from DICOM 3.0 compliant CT scans. Stroke VCAR is designed for the purpose of segmenting and assessing intracerebral and intracranial hemorrhages in the brain using semi-automated tools on non-contrast CT exams. Additionally Stroke VCAR provides a set of workflow tools for the segmentation and visualization of aneurysms in the brain from contrast enhanced CT exams. It is intended for use by clinicians to process, review, archive, print and distribute CT studies.</p> <p>This software will assist the user by providing initial 3D segmentation, measurements and visualization of hemorrhages and aneurysm in the brain. The user has the ability to adjust, review and has to confirm the final segmentation.</p>
<p>Technology:</p>	<p>The Stroke VCAR software employs the same fundamental scientific technology as its predicate device.</p>
<p>Determination of Substantial Equivalence:</p>	<p>Summary of Non-Clinical Tests:</p> <p>The Stroke VCAR software complies with NEMA PS 3.1 - 3.20 (2011) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard.</p> <p>The Stroke VCAR software employs the same fundamental scientific technology as its predicate device (Volume Viewer). Stroke 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. Stroke VCAR utilizes the enhanced segmentation tools (threshold, auto-select) already found in Volume Viewer and optimizes the segmentation algorithms for Hematoma segmentation and Aneurysm segmentation. Thorough testing of these capabilities has not raised any safety or effectiveness issues.</p> <p>The following quality assurance measures were applied to the development of the system:</p> <ul style="list-style-type: none"> ▪ Risk Analysis ▪ Requirements Reviews ▪ Design Reviews ▪ Integration testing (System verification) ▪ Performance testing (Bench testing, validation) ▪ Safety testing (Verification)



	<p>Summary of Clinical tests:</p> <p>A clinical evaluation study using consented clinical images was conducted by three CT technologists in Part 1 and three board certified neuroradiologists in Part 2a and Part 2b who were considered experts. The study was meant to assess the following:</p> <ul style="list-style-type: none"> ▪ Productivity benefits of automated vs. manual hematoma segmentation (Part 1) ▪ General user Qualitative feedbacks of the Stroke VCAR edition tools (Part 2a and Part 2b) <p>The study results demonstrated that the workflow time to perform automated hematoma segmentation utilizing the Stroke VCAR hematoma edition tool was significantly less than the workflow time to perform hematoma segmentation manually.</p> <p>Additionally study results clearly show that Stroke VCAR adds diagnostic value to the current hematoma and aneurysm clinical workflow and is a useful tool for neuroradiologists to providing comprehensive stroke work-up including automated hematoma and aneurysm processing and analysis, quantification and monitoring.</p> <p>The substantial equivalence determination is based on the software documentation for a MODERATE level of concern device.</p>
<p>Conclusion:</p>	<p>GE Healthcare considers the Stroke VCAR software application to be as safe, as effective, and performance is substantially equivalent to the predicate device.</p>