DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 26, 2017

GE Medical Systems SCS
% Ms. Kristine Schraufnagel
Regulatory Affairs Manager
283 rue de la Miniere
Buc, Yvelines 78530
FRANCE

Re: K163281
Trade/Device Name: FastStroke
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 23, 2017
Received: January 24, 2017

Dear Ms. Schraufnagel:

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,

For

Robert Ochs, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163281

Device Name
FastStroke

Indications for Use *(Describe)*
FastStroke is a CT image analysis software package that assists in the analysis and visualization of CT data derived from DICOM 3.0 compliant CT scans. FastStroke is intended for the purpose of displaying vasculature of the head and neck at different time points of enhancement.
The software will assist the user by providing optimized display settings to enable fast review of the images in synchronized formats, aligning the display of the images to the order of the scans and linking together multiple groups of scans. In addition, the software fuses the vascular information from different time points into a single colorized view. This multiphase information can aid the physician in visualizing the presence or absence of collateral vessels in the brain. Collateral vessel information may aid the physician in the evaluation of stroke patients.

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:	January 23, 2017
Submitter:	GE Medical Systems SCS 283, rue de la Minière 78530 Buc, France
Primary Contact Person:	Kristine Schraufnagel Regulatory Affairs Manager Tel: (262) 312 7344 Fax: (262) 548 2317
Secondary Contact Person:	Jeme Ertl Regulatory Affairs Director GE Healthcare Tel: (847) 277 4468 Fax: (847) 277 5240
Device Trade Name:	*FastStroke*
Common/Usual Name:	*FastStroke*
Regulation Number: Regulation Name: Classification Panel: Regulatory Class: Product Code:	21CFR 892.1750 Computed Tomography X-ray System Radiology Class II JAK
Predicate Device: Regulation Number: Regulation Name: Regulation Number: Regulation Name: Regulatory Class: Product Code:	K041521 - Volume Viewer Plus 21CFR 892.1750 Computed Tomography X-ray System 21CFR 892.1000 Magnetic Resonance Diagnostic Device Class II JAK and LNH
Device Description / Intended Use:	***FastStroke*** is a CT image analysis software package that assists in the analysis and visualization of CT data derived from DICOM 3.0 compliant CT scans. *FastStroke* is intended for the

	purpose of displaying vasculature of the head and neck at different time points of enhancement. The software will assist the user by providing optimized display settings to enable fast review of the images in synchronized formats, aligning the display of the images to the order of the scans and linking together multiple groups of scans. In addition, the software fuses the vascular information from different time points into a single colorized view. This multiphase information can aid the physician in visualizing the presence or absence of collateral vessels in the brain. Collateral vessel information may aid the physician in the evaluation of stroke patients. *FastStroke* device has been tested with DICOM images from Discovery CT750 HD and Revolution CT using multi-phase CT Angiography. FastStroke is based on DICOM image based processing and would apply to any CT device that is able to acquire data in an equivalent multi-phase CT angiography (pursuant to the timing protocols in the user guide) manner. *FastStroke* is also made available as a standalone post processing application on the AW VolumeShare workstation (K110834) and AW Server platform (K081985) that host advanced image processing applications.

Indications for Use:	***FastStroke*** is a CT image analysis software package that assists in the analysis and visualization of CT data derived from DICOM 3.0 compliant CT scans. *FastStroke* is intended for the purpose of displaying vasculature of the head and neck at different time points of enhancement. The software will assist the user by providing optimized display settings to enable fast review of the images in synchronized formats, aligning the display of the images to the order of the scans and linking together multiple groups of scans. In addition, the software fuses the vascular information from different time points into a single colorized view. This multiphase information can aid the physician in visualizing the presence or absence of collateral vessels in the brain. Collateral vessel information may aid the physician in the evaluation of stroke patients.
Technology:	The FastStroke software employs the same fundamental scientific technology as its predicate device.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The FastStroke software complies with NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard. The FastStroke software employs the same fundamental scientific technology as its predicate device (Volume Viewer). FastStroke software uses the equivalent CT DICOM image data input requirements. It has equivalent display, formatting, archiving and visualization technologies compared to the predicate device. FastStroke utilizes the thresholding and fusion tools already found in Volume Viewer and optimizes them to display either a synchronized multi-time point display or a single color coded fused display. 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, validation) ▪ Safety testing (Verification)

	Summary of Clinical tests: A retrospective clinical evaluation was conducted by three board certified neuroradiologists who were considered experts. The primary endpoint of the study was meant to assess the following using multiple 5-point Likert Scales: • Demonstrate increased diagnostic capability of FastStroke in a clinical setting of acute stroke. The study results show that FastStroke aids the physician in visualizing the presence or absence of collateral vessels in the brain and is a useful tool for neuroradiologists in providing a comprehensive stroke work-up. The substantial equivalence determination is based on the software documentation for a MODERATE level of concern device.
Conclusion:	GE Healthcare considers the FastStroke software application to be as safe, as effective, and performance is substantially equivalent to the predicate device.