November 12, 2020

GE Medical Systems SCS
% Ms. Elizabeth Mathew
Senior Regulatory Affairs Manager
283 rue de la Miniere
Buc, 78530
FRANCE

Re: K193289
Trade/Device Name: FastStroke, CT Perfusion 4D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK, LLZ
Dated: October 7, 2020
Received: October 8, 2020

Dear Ms. Mathew:

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/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,

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)*

K193289

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.

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

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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)*
K193289

Device Name

CT Perfusion 4D

Indications for Use *(Describe)*

CT perfusion 4D is an image analysis software package that allows the user to produce dynamic image data and to generate information with regard to changes in image intensity over time. It supports the analysis of CT perfusion images (in the head and body) after the intravenous injection of contrast, in calculation of the various perfusion-related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability). The results are displayed in a user-friendly graphic format as parametric images.

This software will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes, which may be related to stroke or tumor angiogenesis and the treatment thereof.

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)

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510(k) Summary K193289

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

Date:	November 5, 2020
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Elizabeth Mathew Senior Regulatory Affairs Manager GE Healthcare, (GE Medical Systems, LLC) 3000 N Grandview Blvd., Waukesha, WI - 53188 Phone: (262) 424-7774 Email: Elizabeth.Mathew@ge.com
Secondary Contact Person:	Helen Peng Sr. Regulatory Affairs Director GE Healthcare, (GE Medical Systems, LLC) 3000 N Grandview Blvd., Waukesha, WI - 53188 Phone: 262-424-8222 Email: Hong.Peng@ge.com
Proposed Device:	
Device Name:	FastStroke, CT Perfusion 4D
Common/Usual Name:	FastStroke, CT Perfusion 4D FastStroke Gen 2
Primary Regulation number: Primary Product Code:	CFR 892.1750 Computed Tomography X-Ray System JAK
Secondary Regulation number:	21 CFR 892.2050 Picture archiving and communications system
Secondary Product Code:	LLZ
Classification:	Class II

Predicate Device:	
Device Name:	FastStroke
510(k) number:	K163281 cleared on January 26, 2017
Regulation number/ Product Code:	21 CFR 892.1750 Computed Tomography X-Ray System JAK
Classification:	Class II
Manufacturer:	GE Medical Systems SCS
Predicate Device:	
Device Name:	CT Perfusion 4
510(k) number:	K052839 cleared on March 10, 2006
Regulation number/ Product Code:	21 CFR 892.1750 Computed Tomography X-Ray System JAK
Classification:	Class II
Manufacturer:	GE Medical Systems SCS

Device Description:

NeuroPackage is a solution which contains two medical devices FastStroke and CT Perfusion 4D (Neuro) in order to help streamline the CT Stroke Workflow. The configuration of NeuroPackage enables the user to open a single application, FastStroke, which provides them access to both the updated CT Perfusion 4D and FastStroke applications. However, same as the predicate devices, the capabilities in CT Perfusion 4D and FastStroke can be offered independently.

CT perfusion 4D is an image analysis software package, which allows the user to produce dynamic image data and to generate information with regards to changes in image intensity over time. It supports the analysis of CT Perfusion images (in the head and body) after the intravenous injection of contrast, and calculation of the various perfusion-related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability). The results are displayed in a user-friendly graphic format as parametric images.

This software will aid in the assessment of the extent and type of perfusion, blood volume, and capillary permeability changes, which may be related to stroke or tumor angiogenesis and the treatment thereof.

FastStroke is a CT image analysis software package intended for the purpose of displaying stroke workup images (i.e. vasculature of the head, non-contrast head and neck at different time points of enhancement) in a single software, using an optimized workflow. The software is compatible with DICOM 3.0 images and will assist the user by providing dedicated review steps and optimized display settings to enable fast review of the images in synchronized formats. In addition, if a multiphase CT Angiogram has been acquired, the software will fuse the vascular information from these 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, as well as their delay.

All features from the CT Perfusion 4D Neuro software are accessible in the Perfusion, Set Symmetry and Tissue Classification steps within FastStroke Application, seamlessly introduced in an integrated workflow.

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.

CT perfusion 4D is an image analysis software package that allows the user to produce dynamic image data and to generate information with regard to changes in image intensity over time. It supports the analysis of CT perfusion images (in the head and body) after the intravenous injection of contrast, in calculation of the various perfusion-related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability). The results are displayed in a user-friendly graphic format as parametric images.

This software will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes, which may be related to stroke or tumor angiogenesis and the treatment thereof.

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.

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parametric images.
This software will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes, which may be related to stroke or tumor angiogenesis and the treatment thereof.

Technological Characteristic:

NeuroPackage solution contains modified FastStroke and CT Perfusion 4D applications. For the modified Faststroke software, there is no change in technology with respect to the clinical functionality of the software. However modified FastStroke and CT Perfusion 4D software contain an additional export capability in order to enable the email notification feature. The modified CT Perfusion 4D software employs a deep learning convolutional neural network to segment the brain ventricles while the predicate device uses a manual method based on HU thresholding. There is no technology change in comparison to the predicate device for the changes to Tissue Classification in the modified CT Perfusion 4D software. 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.

Comparison

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

FastStroke:

Specification	**Predicate Device FastStroke (K163281)**	**Proposed Device FastStroke**	**Comparison**
Send Email Feature	Not Available	Results from preprocessing will be populated into email and sent to pre-defined distribution list automatically.	**Substantial Equivalent** Improved method to distribute the report to facilitate user workflow

CT Perfusion 4D:

Specification	**Predicate Device CT Perfusion 4 (K052839)**	**Proposed Device CT Perfusion 4D**	**Comparison**
Map Creation	Automatic based on HU thresholding	Automatic Deep Learning Algorithm	**Substantial Equivalent** Improved method for removing ventricles
Tissue Classification	In tissue classification it is restricted which input parameters can be used (Blood Volume only for	In tissue classification there is no restriction as the software allows the user to select from 4 input	**Substantial Equivalent** Proposed device allows additional input maps

	1st segmentation, Blood Flow, TMax or MTT only for modified perfusion).	parameters (Blood Volume, Blodd Flow, TMax, MTT) to generate the tissue classification display.	for Tissue Classification
Send Email Feature	Manual method to export the report.	Report with the images will be populated into email and sent to pre-defined distribution list automatically.	**Substantial Equivalent** Improved method to distribute the report

Determination of Substantial Equivalence:

NeuroPackage solution which contains FastStroke and CT Perfusion 4D software has successfully completed the required design control activities per GE's quality management system that complies to 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 and Mitigation
- Requirements Reviews
- Design Reviews
- Performance testing (Verification, Validation)
- Safety testing (Verification)

For the brain ventricle segmentation deep learning algorithm, bench tests that compare the output of the new algorithm with ground truth annotated by qualified experts show that the algorithm performed as expected.

The software testing and the corresponding results for all the other changes in FastStroke and CT Perfusion 4D software contained in NeuroPackage solution did not raise new questions of safety and effectiveness from those associated with predicate devices and demonstrated that modified FastStroke and CT Perfusion 4D performs substantially equivalent to the predicate devices.

The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Conclusion

GE Healthcare considers the modifications to FastStroke and CT Perfusion 4D contained within the NeuroPackage solution to be as safe, as effective as the predicate devices, and is substantially equivalent to the predicate devices.