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

March 1, 2017

Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
40 Liberty Boulevard
Mail Code 65-1A
MALVERN PA 19355

Re: K163284
Trade/Device Name: syngo.CT Neuro Perfusion
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 14, 2017
Received: February 16, 2017

Dear Ms. Mangum:

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)*
K163284

Device Name
syngo.CT Neuro Perfusion

Indications for Use *(Describe)*
The syngo.CT Neuro Perfusion software package is designed to evaluate areas of brain perfusion. The software processes images or volumes that were reconstructed from continuously acquired CT data after the injection of contrast media.
It generates the following result volumes:
• Cerebral blood flow (CBF)
• Cerebral blood volume (CBV)
• Local bolus timing (time to start (TTS), time to peak (TTP), time to drain (TTD))
• Mean transit time (MTT)
• Transit time to the center of the IRF (TMax)
• Flow extraction product (permeability)
• Temporal mip
• Temporal average
• Baseline volume
• Modified dynamic input data

The software also allows the calculation of mirrored regions or volumes of interest and the visual inspection of time attenuation curves. One clinical application is to visualize the apparent blood perfusion and the parameter mismatch in brain tissue affected by acute stroke.
Areas of decreased perfusion appear as areas of changed signal intensity:
• Lower signal intensity for CBF and CBV
• Higher signal intensity for TTP, TTD, MTT, and TMax

A second application is to visualize blood brain barrier disturbances by modeling extravascular leakage of blood into the interstitial space. This additional capability may improve the differential diagnosis of brain tumors and be helpful in therapy monitoring.

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."

SIEMENS

510(K) SUMMARY
FOR
SYNGO.CT NEURO PERFUSION

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Date Prepared: January 20, 2017

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. Submitter
Importer/Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Establishment Registration Number
2240869

Manufacturing Site
Siemens Healthcare GmbH
Siemensstr. 1
D-91301 Forchheim, Germany

Establishment Registration Number
3004977335

Contact Person
Kimberly Mangum
Regulatory Affairs Specialist
Siemens Medical Solutions, Inc. USA
40 Liberty Boulevard
Malvern, PA 19355
Phone: (610) 448 - 6477
Fax: (610) 640 - 4481
Email: kimberly.mangum@siemens.com

II. Device Name and Classification

510(k) Number:	K163284
Product Name:	syngo.CT Neuro Perfusion
Propriety Trade Name:	syngo.CT Neuro Perfusion
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

SIEMENS

III. Predicate Device

Predicate Device:

Trade Name:	syngo.CT Neuro Perfusion
510(k) Number:	K123541
Clearance Date:	04/02/2013
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

Reference Device:

Trade Name:	RAPID
510(k) Number:	K121447
Clearance Date:	10/04/2013
Classification Name:	Picture archiving and communications system
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.2050
Device Class:	Class II
Product Code:	LLZ

IV. Device Description

The syngo.CT Neuro Perfusion software allows the quantitative evaluation of dynamic CT data of the brain acquired during the injection of a compact bolus of iodinated contrast material. It mainly aids in the early differential diagnosis of acute ischemic stroke. The Blood-brain-barrier (BBB) imaging feature supports the diagnostic assessment of brain tumors.

By providing images of e.g. cerebral blood flow (CBF), cerebral blood volume (CBV), time to peak (TTP), and Mean Transit Time (MTT) from one set of dynamic CT images or volumes, syngo.CT Neuro Perfusion allows a quick and reliable assessment of the type and extent of cerebral perfusion disturbances, including fast evaluation of the tissue at risk and non-viable tissue in the brain. The underlying approaches for this application were cleared as part of the predicate device and remain unchanged in comparison to the predicate device.

syngo.CT Neuro Perfusion allows simultaneous multi-slice processing and supports the workflow requirements in a stroke workflow. The availability of flow extraction product imaging extends the option to the diagnosis of brain tumors. A listing of device modifications as part of the new software version VB20 of syngo.CT Neuro Perfusion is as follows:

- Auto Stroke Workflow
  (Calculation and display of the stroke results without user input)
- Rapid Results Technology
  (Calculates stroke results and quality control images without user input and sends all images to other DICOM nodes)
- Additional Parameters for Penumbra and Core Infarct Calculation

This software is designed to operate on at least the syngo.via VB20 hardware/software platform, and should be used with reconstructed images that meet the following minimum requirements:

- Images should be reconstructed with the high sampling frequency. Scan modes are e. g. adaptive 4D spiral, Dynamic sequence and dynamic multi-scan modes of Siemens CT scanners.
- A standard reconstruction kernel should be used
- Images should be reconstructed with an increment smaller than the slice thickness to achieve good resolution

V. Indications for Use

The syngo.CT Neuro Perfusion software package is designed to evaluate areas of brain perfusion. The software processes images or volumes that were reconstructed from continuously acquired CT data after the injection of contrast media.
It generates the following result volumes:

- Cerebral blood flow (CBF)
- Cerebral blood volume (CBV)
- Local bolus timing (time to start (TTS), time to peak (TTP), time to drain (TTD))
- Mean transit time (MTT)
- Transit time to the center of the IRF (TMax)
- Flow extraction product (permeability)
- Temporal MIP
- Temporal Average
- Baseline Volume
- Modified dynamic input data

The software also allows the calculation of mirrored regions or volumes of interest and the visual inspection of time attenuation curves. One clinical application is to visualize the apparent blood perfusion and the parameter mismatch in brain tissue affected by acute stroke. Areas of decreased perfusion appear as areas of changed signal intensity:

- Lower signal intensity for CBF and CBV
- Higher signal intensity for TTP, TTD, MTT, and TMax

A second application is to visualize blood brain barrier disturbances by modeling extravascular leakage of blood into the interstitial space. This additional capability may improve the differential diagnosis of brain tumors and be helpful in therapy monitoring.

VI. Comparison of Technological Characteristics with the Predicate Device

The evaluation of tissue perfusion is the technological principle for both the subject and predicate devices. Both devices have the same Intended Use, same Indications for Use and similar visualization and evaluation technological characteristics. At a high-level, the subject and predicate device are based on the following same/similar technological characteristics:

Feature	Subject Device	Predicate Device	Comparison
Purpose of the application	visualization of tissue perfusion using rapid sequences collected after the administration of contrast medium	visualization of tissue perfusion using rapid sequences collected after the administration of contrast medium	Same
Acquisition	patient scan following administration of contrast media	patient scan following administration of contrast media	Same

SIEMENS

Feature	Subject Device	Predicate Device	Comparison
CT Scanning Mode	Scanning at a single table position or using spirals with the same scan range	Scanning at a single table position or using spirals with the same scan range	Same
Motion Correction	Rigid motion correction which can be used in brain datasets	Rigid motion correction which can be used in brain datasets	Same
Time Point Removal	On user request time points and time ranges (time point volumes) can be removed from the current evaluation if they show strong patient or organ movement.	On user request time points and time ranges (time point volumes) can be removed from the current evaluation if they show strong patient or organ movement.	Same
4D Noise Reduction	Noise reduction with preservation of time-attenuation information can be performed to improve the image quality of noisy input images and to allow for robust image evaluation	Noise reduction with preservation of time-attenuation information can be performed to improve the image quality of noisy input images and to allow for robust image evaluation	Same
Brain Segmentation	The task can apply the brain segmentation algorithm	The task can apply the brain segmentation algorithm	Same
HU Segmentation	Removes all pixels that lie outside the Min HU and Max HU thresholds	Removes all pixels that lie outside the Min HU and Max HU thresholds	Same
Reference Vessel Definition	Automatic identification of the reference vessel with simple interactive override if the user does not accept automatic detection	Automatic identification of the reference vessel with simple interactive override if the user does not accept automatic detection	Same
Vessel and Arteries Definition	Automatic identification of the brain vessels and arteries with simple interactive override possibility	Automatic identification of the brain vessels and arteries with simple interactive override possibility	Same
Hemisphere Plane Definition	Automatic hemisphere plane definition which can be manually corrected	Automatic hemisphere plane definition which can be manually corrected	Same
Normalization	Normalization of CBF and CBV values based on a histogram analysis of the non-ischemic hemisphere	Normalization of CBF and CBV values based on a histogram analysis of the non-ischemic hemisphere	Same
Result Storage	Storage of all result images in the database as DICOM CT grayscale, color RGB, Enhanced CT	Storage of all result images in the database as DICOM CT grayscale, color RGB, Enhanced CT	Same
ROI (region of interest) evaluation	ROI (region of interest) measurements with calculation of mean value, standard deviation and area for detailed analysis of specific ischemic areas	ROI (region of interest) measurements with calculation of mean value, standard deviation and area for detailed analysis of specific ischemic areas	Same
ROI mirroring	Mirroring of the ROIs at the hemisphere plane and output of statistical parameters like mean value, standard deviation and area	Mirroring of the ROIs at the hemisphere plane and output of statistical parameters like mean value, standard deviation and area	Same

Feature	Subject Device	Predicate Device	Comparison
TAC display	Parallel display of several time attenuation curves	Parallel display of several time attenuation curves	Same
Automatic Stroke calculation	Automatic calculation of all steps, visualization of all intermediate results allowing a final result check	Manual assessment of each calculation step including a result check	**Equivalent**
Sending of Images to PACS	Automatic sending of result images to PACS including quality control images. Possibility to do the evaluation manually.	Sending of images to PACS after manual assessment of the results	**Equivalent**
Tissue at risk and non-viable tissue visualization	The flexible penumbra analysis mode allows highlighting of areas as Non-viable Tissue (NVT) and Tissue At Risk (TAR) according to certain user defined thresholds. Thresholds of two different Perfusion maps, e.g. CBF, CBV, MTT, TTP can be used. Results can be smoothed to reduce artifacts. Relative thresholds can be used for CBV and CBF. The visualization is done as color coded overlay on temporal MIP. Additional TAC and statistical values are displayed	The flexible penumbra analysis mode allows highlighting of areas as Non-viable Tissue (NVT) and Tissue At Risk (TAR) according to certain user defined thresholds. Thresholds of two different Perfusion maps, e.g. CBF, CBV, MTT, TTP can be used. The visualization is done as color coded overlay on temporal MIP. Additional TAC and statistical values are displayed	**Modified**
User Interface	syngo.via GUI	syngo.via GUI	Same
Archiving/ Storing	CD-R, film, DVD, USB, Network	CD-R, film, DVD, USB, Network	Same
Hardware	As specified by syngo.via	As specified by syngo.via	Same
Communication	DICOM compatible	DICOM compatible	Same

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination. This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted for syngo.CT Neuro Perfusion during product development. The modifications described in this Premarket Notification were supported with verification/validation testing.

Risk Analysis

The risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence

Software Verification and Validation

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission.

SIEMENS

Non-Clinical Testing Summary

Performance tests were conducted to test the functionality of the syngo.CT Neuro Perfusion. These tests have been performed to test the ability of the included features of the subject device. The results of these tests demonstrate that the subject device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. syngo.CT Neuro Perfusion is designed to fulfill the requirements of the following safety and performance standards:

Recognition Number	Product Area	Title of Standard	Publication Date	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-32	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)	08/20/2012	AAMI, ANSI, IEC
5-40	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01	08/20/2012	ISO
5-95	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	06/27/2016	IEC
19-4	General II (ES/EMC)	AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, mod)	07/09/2014	AAMI, ANSI

VIII. Conclusions

syngo.CT Neuro Perfusion has the same intended use and indication for use as the predicate device. The technological characteristics such as image visualization and image manipulation are the same as the predicate device. The result of all testing conducted was found acceptable to support the claim of substantial equivalence. The predicate devices were cleared based on non-clinical supportive information. The results of these tests demonstrate that the predicate devices are adequate for the intended use. The comparison of technological characteristics, non-clinical performance data, and software validation demonstrates that the subject device is as safe and effective when compared to the predicate device that is currently marketed for the same intended use. For the subject device, syngo.CT Neuro Perfusion, Siemens used the same testing with the same workflows as used to clear the predicate device. Since both devices were tested using the same methods, Siemens believes that the data generated from the syngo.CT Neuro Perfusion testing supports a finding of substantial equivalence.