Siemens Medical Solutions USA, Inc.
% Tabitha Estes
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE TN 37932

January 28, 2022

Re: K203260
Trade/Device Name: syngo.CT Brain Hemorrhage
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: December 15, 2021
Received: December 17, 2021

Dear Tabitha Estes:

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,

For

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203260

Device Name
syngo.CT Brain Hemorrhage

Indications for Use *(Describe)*
syngo.CT Brain Hemorrhage is designed to assist the radiologist in prioritizing cases of suspected intracranial hemorrhage on non-contrast CT examinations of the head. It makes case-level output available to a CT scanner or other PACS system for worklist prioritization. The output is intended for informational purposes only and is not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a stand-alone diagnostic device.

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.

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510(K) SUMMARY
FOR
SYNGO.CT BRAIN HEMORRHAGE
K203260

Date Prepared: January 26th, 2022

Identification of the 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

Submitter Contact Person:
Tabitha Estes
Regulatory Affairs Specialist
Siemens Medical Solutions, Inc. USA
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Knoxville, TN 37932
Phone: (865) 804-4553
Email: tabitha.estes@siemens-healthineers.com

Alternate Contact:
Alaine Medio

I. Device Name and Classification

Product Name:	syngo.CT Brain Hemorrhage
Propriety Trade Name:	syngo.CT Brain Hemorrhage
Classification Name:	Radiological Computer-Assisted Triage and Notification Software
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2080
Device Class:	Class II
Product Code:	QAS

II. Predicate Device

Trade Name:	Accipiolx
510(k) Number:	K182177
Clearance Date:	07/26/2019
Classification Name:	Radiological Computer-Assisted Triage and Notification Software
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2080
Device Class:	Class II
Product Code:	QAS

III. Device Description

The subject device syngo.CT Brain Hemorrhage is an image processing software that utilizes artificial intelligence learning algorithms to support qualified clinicians in analysis and prioritization of non-contrast head CT DICOM images by algorithmically identifying findings suspicious of acute intracranial hemorrhage. The subject device provides a pipeline for the analysis and identification of potential ICH as well as a finding notification mechanism.

IV. Indications for Use

syngo.CT Brain Hemorrhage is designed to assist the radiologist in prioritizing cases of suspected intracranial hemorrhage on non-contrast CT examinations of the head. It makes case-level output available to a CT scanner or other PACS system for worklist prioritization. The output is intended for informational purposes only and is not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a stand-alone diagnostic device.

V. Comparison of Technological Characteristics with the Predicate Device

The differences and similarities between the above referenced predicate device are listed at a high-level in the following table:

Feature	Subject Device	Predicate Device	Comparison Table
	syngo.CT Brain Hemorrhage	MaxQ-AI AccipioIx	
Notification-only, parallel workflow tool	Yes	Yes	Same
Intended User	Hospital networks and qualified clinicians	Hospital networks and qualified clinicians	Same
Setting	Acute Care	Acute Care	Same
Identify patients with a prespecified clinical condition	Yes	Yes	Same
Clinical condition	Intracranial hemorrhage	Intracranial hemorrhage	Same
Alert to finding	Yes; flagged for review	Yes; flagged for review	Same
Independent of standard of care workflow	Yes; No cases are removed from worklist	Yes; No cases are removed from worklist	Same
Modality	Non-contrast CT	Non-contrast CT	Same
Body Part	Head	Head	Same
Artificial Intelligence algorithm	Yes	Yes	Same
Limited to analysis of imaging data	Yes	Yes	Same

Feature	Subject Device	Predicate Device	Comparison Table
	syngo.CT Brain Hemorrhage	MaxQ-AI AccipioIx	
Output	Suspected hemorrhage / No suspected hemorrhage	Suspected hemorrhage / No suspected hemorrhage	Same

The subject device syngo.CT Brain Hemorrhage does not have changes in fundamental scientific technology compared to the predicate device. The post-processing software functionality remains unchanged from the subject device and the predicate device. The operating principle and the scientific technology are the same; therefore, Siemens believes that syngo.CT Brain Hemorrhage application is substantially equivalent to the predicate device.

VI. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Testing
Non-clinical tests (integration and functional) were conducted for syngo.CT Brain Hemorrhage during product development. 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 results of all conducted testing were found acceptable to support the claim of substantial equivalence.

Performance Evaluation of the Algorithm
The performance of the syngo.CT Brain Hemorrhage device has been validated in a retrospective stand-alone performance study. Sensitivity and specificity of syngo.CT Brain Hemorrhage in processing of non-contrast head CT have been analyzed by comparison to a ground truth established by majority read of 3 US board certified neuroradiologists with more than 10 years of experience. The data cohort consisted of 600 anonymized head CT cases from 5 sites in US and Europe with approximately equal distribution of positive (case with ICH) and negative (case without ICH) cases.

Sensitivity was observed to be 92.8% (95% CI: 89.3%-95.2%). Specificity was observed to be 94.5% (95% CI: 91.3%-96.5%). Thus, sensitivity and specificity exceeded the 80% performance goal.

The average per-case processing time was 13.67 seconds (95% CI: 7.48-19.86 seconds). This is comparable to the predicate device.

To conclude, syngo.CT Brain Hemorrhage is a safe and effective triage and notification device for intracranial hemorrhages which is substantially equivalent to the predicate device.

Siemens hereby certifies that syngo.CT Brain Hemorrhage will meet the following voluntary standards covering electrical and mechanical safety listed below, prior to introduction into interstate commerce:

Recognition Number	Product Area	Title of Standard	Date of Recognition	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-79	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)	01/14/2019	AAMI, ANSI, IEC
5-40	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01	06/27/2016	ISO
5-114	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	12/23/2016	IEC

VII. Conclusion

syngo.CT Brain Hemorrhage has the same intended use and similar indication for use as the predicate device. The result of all testing conducted was found acceptable to support the claim of substantial equivalence. The comparison of technological characteristics, clinical and 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. Siemens considers syngo.CT Brain Hemorrhage to be as safe, as effective and with performance substantially equivalent to the commercially available predicate device.