Siemens Medical Solutions USA, Inc.
Monsuru Bello
Regulatory Affairs Specialist
810 Innovation Drive
Knoxville, TN 37932

March 22, 2024

Re: K232431
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: February 21, 2024
Received: February 21, 2024

Dear Monsuru Bello:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Lamb

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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.*

Submission Number *(if known)*

K232431

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, also in the subarachnoid space, 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 standalone 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.**

# 510(k) Summary

## 1. Identification of the Submitter

| | |
|---|---|
| **Submitter / Primary Contact Person** | Monsuru (Kenny) Bello<br>Regulatory Affairs<br>monsuru.bello@siemens-healthineers.com<br>+1(240) 601-3848 |
| **Secondary Contact Person** | Clayton Ginn<br>Regulatory Affairs<br>clayton.ginn@siemens-healthineers.com<br>+1 (865) 898-2692 |
| **Submitter Address** | Siemens Medical Solutions, Inc. USA<br>Molecular Imaging<br>810 Innovation Drive<br>Knoxville, TN 37932<br>Establishment Registration Number: 1034973 |
| **Legal Manufacturer** | Siemens Healthcare GmbH<br>SIEMENSSTRASSE 1 -OR-<br>Rittigfeld 1<br>FORCHHEIM Bavaria, DE 91301<br>Establishment Registration Number: 3004977335 |
| **Importer/Distributor** | Siemens Medical Solutions USA, Inc.<br>40 Liberty Boulevard<br>Malvern, PA 19355<br>Establishment Registration Number: 2240869 |

## 2. 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 |

## 3. Predicate Device

| | |
|---|---|
| Trade Name: | syngo.CT Brain Hemorrhage |
| 510(k) Number: | K203260 |
| Clearance Date: | 01/28/2022 |
| 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 |

## 4. Device Description

The subject device syngo.CT Brain Hemorrhage is an image-processing software that uses an artificial intelligence algorithm to support qualified clinicians in the analysis and prioritization of non-contrast head CT images. It is a notification-only processing application that algorithmically identifies findings suspicious of acute intracranial hemorrhage (ICH) and acute subarachnoid hemorrhage (SAH). The subject device facilitates a parallel workflow, where cases suspected of presence of ICH or SAH are flagged. The device does not mark, highlight, or direct users' attention to a specific location in the original image. The device does not remove cases from a reading queue.

The subject device syngo.CT Brain Hemorrhage is an improved and extended version of the predicate device (syngo.CT Brain Hemorrhage, K203260, clearance date 01/28/2022). The differences to the predicate device can be summarized as:

- Improved algorithm model for the triage of intracranial hemorrhage (ICH), targeting a higher sensitivity for cases with smaller hemorrhages.
- Extension of the device output to the triage of subarachnoid hemorrhages (SAH), a subtype of intracranial hemorrhages (ICH).
- Support of DICOM conformant head CT reconstructions fulfilling diagnostic quality for the identification of ICH, without restriction to be acquired with a Siemens CT scanner
- Additional deployment compatibility with the syngo.via host system.

## 5. Indications for Use

syngo.CT Brain Hemorrhage is designed to assist the radiologist in prioritizing cases of suspected intracranial hemorrhage, also in the subarachnoid space, 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 standalone diagnostic device.

## 6. 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 *(SOMARIS/8 VB80)* | syngo.CT Brain Hemorrhage *(SOMARIS/8 VB60)* | |
| Notification-only, parallel workflow tool | Yes | Yes | Same |
| Intended User | Radiologists and clinical administrators | Radiologists and clinical administrators | Same |
| Setting | Acute Care | Acute Care | Same |

| Feature | Subject Device | Predicate Device | Comparison Table |
|---|---|---|---|
| | syngo.CT Brain Hemorrhage *(SOMARIS/8 VB80)* | syngo.CT Brain Hemorrhage *(SOMARIS/8 VB60)* | |
| Identify patients with a prespecified clinical condition | Yes | Yes | Same |
| Clinical condition | Intracranial hemorrhage, Subarachnoid hemorrhage | Intracranial hemorrhage | Extended |
| 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 |
| Training Data | 29 713 cases | 28 814 cases | Improved |
| Limited to analysis of imaging data | Yes | Yes | Same |
| Scanner Manufacturer of Input Data | Siemens and other vendors | Siemens | Extended |
| Output | Suspected hemorrhage / Suspected hemorrhage including the subarachnoid space / Processing finished | Suspected hemorrhage / Processing finished | Extended |
| Deployment Compatibility | SOMARIS-X platform, syngo.via platform | SOMARIS-X platform | Extended |

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.

## 7. Performance Data

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

**Non-Clinical Testing**

This submission contains performance tests (Non-clinical test reports) to demonstrate continued conformance with special controls for medical devices containing software. 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 900 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.

For the triage of intracranial hemorrhage, the sensitivity was 95.0% (95% CI: 92.5%-96.7%) and the specificity was 93.1% (95% CI: 90.5%-95.1%). Thus, sensitivity and specificity exceeded the 80% performance goal.

For the triage of subarachnoid hemorrhage, the sensitivity was 86.1% (95% CI: 81.1%-90.0%) and the specificity was 85.2% (95% CI: 82.3%-87.7%). Thus, sensitivity and specificity exceeded the 80% performance goal.

The average per-case processing time was 13.34 seconds (95% CI: 9.16-17.51 seconds). This is comparable to the predicate device (13.67 seconds, 95% CI: 7.48-19.86).

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:

| Standard | Version | Content | FDA Recognition Number (if applicable) |
|---|---|---|---|
| ANSI AAMI IEC 62304 | :62304:2006/A1:2016 | Medical device software - Software life cycle processes [Including Amendment 1 (2016)] | 13-79 |
| NEMA PS 3.1 - 3.20 2022d | :2022 | Digital Imaging and Communications in Medicine (DICOM) Set | 12-349 |
| ISO 14971 | :2019 | Application of Risk Management to Medical Devices | 5-125 |
| IEC 62366-1 | Edition 1.1 2020-06 CONSOLIDATED VERSION | Medical devices - Part 1: Application of usability engineering to medical devices | 5-129 |
| ISO 15223-1 | Fourth edition 2021-07 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements | 5-134 |
| ISO 20417:2021 | First edition 2021-04 Corrected version 2021-12 | Medical devices - Information to be supplied by the manufacturer | 5-135 |

## 8. 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.