April 10, 2025

Siemens Medical Solutions USA, Inc.
Kenny M. Bello
Regulatory Affairs Professional
810 Innovation Drive
Knoxville, Tennessee 37932

Re: K243145
Trade/Device Name: syngo.CT LVO Detection
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: March 4, 2025
Received: March 4, 2025

Dear Kenny M. 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243145

Device Name
syngo.CT LVO Detection

Indications for Use *(Describe)*
syngo.CT LVO Detection is a radiological post-processing application for the analysis of CT angiography (CTA) head images. syngo.CT LVO Detection supports computer-aided triage, and it addresses vascular abortions in the CTA of the brain, commonly referred to as large vessel occlusion (LVO), in the ICA, M1, and M2 segment. It is intended for all patient populations of age ≥ 22 years, without any of the following contraindications: old infarcts or other diseases impacting the brain vasculature (for example, brain tumors), metal artifacts (for example, coils), surgical signs in the images. The output for triage is intended for informational purposes only. It is not intended for diagnostic use and does not alter the original medical image.

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.

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510(k) Summary

1. Identification of the Submitter

Submitter / Primary Contact Person	Kenny M Bello Regulatory Affairs monsuru.bello@siemens-healthineers.com +1(202) 856-6099
Secondary Contact Person	Clayton Ginn Regulatory Affairs clayton.ginn@siemens-healthineers.com +1 (865) 898-2692
Submitter Address	Siemens Medical Solutions, Inc. USA Molecular Imaging 810 Innovation Drive Knoxville, TN 37932 Establishment Registration Number: 1034973
Legal Manufacturer	Siemens Healthineers AG Siemensstr 1 D-91301 Forchheim, Germany Establishment Registration Number: 3004977335
Importer/Distributor	Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard Malvern, PA 19355 Establishment Registration Number: 2240869

2. Device Name and Classification

Product Name:	*syngo.*CT LVO Detection
Propriety Trade Name:	*syngo.*CT LVO Detection
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 Devices

Predicate Device:

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
K-Number:	K232431

4. Device Description

The subject device syngo.CT LVO Detection is an image processing software that utilizes artificial intelligence learning algorithms to support qualified clinicians (Radiologists, Neuroradiologists, Neurologists) in prioritization of CT-angiography images by algorithmically identifying findings suspicious of a large vessel occlusion and providing notification to the user. syngo.CT LVO Detection provides a reproducible detection of large vessel occlusions (LVO) on contrast-enhanced CT examinations of the head for detection of ICA, M1, and M2 vessel occlusions in patients suspected of having stroke related circulation occlusion. syngo.CT LVO Detection analyses CT-angiography (CTA) images of the head. The subject device provides a pipeline for the analysis and identification of potential LVO The output which can be send to an external notification device does not highlight or direct attention of the reading physician to any portion of the image.

5. Indications for Use

syngo.CT LVO Detection is a radiological post-processing application for the analysis of CT angiography (CTA) head images. syngo.CT LVO Detection supports computer-aided triage, and it addresses vascular abortions in the CTA of the brain, commonly referred to as large vessel occlusion (LVO), in the ICA, M1, and M2 segment. It is intended for all patient populations of age ≥ 22 years, without any of the following contraindications: old infarcts or other diseases impacting the brain vasculature (for example, brain tumors), metal artifacts (for example, coils), surgical signs in the images. The output for triage is intended for informational purposes only. It is not intended for diagnostic use and does not alter the original medical image.

6. Indications for Use Comparison to the Predicate Device

Subject Device syngo.CT LVO Detection *(SOMARIS/8 VB80)*	**Predicate Device** syngo.CT Brain Hemorrhage *(SOMARIS/8 VB80)*
syngo.CT LVO Detection is a radiological post-processing application for the analysis of CT angiography (CTA) head images. syngo.CT LVO Detection supports computer-aided triage, and it addresses vascular abortions in the CTA of the brain, commonly referred to as large vessel occlusion (LVO), in the ICA, M1, and M2 segment. The output for triage is intended for informational purposes only. It is not intended for diagnostic use and does not alter the original medical image.	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.

Both applications are designed to analyze head CT scans using artificial intelligence-based algorithms. The intention is to assist the radiologist in prioritizing cases by providing a notification of suspected acute findings on CT.

7. Comparison of Technological Characteristics with the Predicate Device

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

Feature	Subject Device	Predicate Device	Comparison
	syngo.CT LVO Detection (SOMARIS/8 VB80) *(K243145)*	**syngo.CT Brain Hemorrhage (SOMARIS/8 VB80) *(K232431)***	
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
Identify patients with a prespecified clinical condition	Yes	Yes	Same
Clinical condition	Suspected Stroke/LVO	Suspected Stroke/Brain Hemorrhage	Same
Alert to finding	Yes; flagged for review	Yes; flagged for review	Same
Primary Imaging Modalities	CT	CT	Same
Body Part	Head	Head	Same
Artificial Intelligence algorithm	Yes	Yes	Same
Limited to analysis of imaging data	Yes	Yes	Same
Scanner Manufacturer of Input Data	Siemens and other vendors	Siemens and other vendors	Same
Output	Suspected LVO/ Processing finished	Suspected hemorrhage/ Processing finished	Similar
Deployment Compatibility	syngo.via platform	syngo.via platform, SOMARIS-10 platform	Similar

8. Performance Data

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

Software Verification and Validation

Software Documentation for Enhanced documentation Level per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, is also included as part of this submission. The Risk Analysis was completed, and risk control implemented

to mitigate identified hazards. The testing supports that all software specifications have met the acceptance criteria. Testing for verification and validation support the claim of substantial equivalence.

Summary of Performance Testing

Standalone testing was performed on 602 retrospective CT data sets from 602 individual patients from 4 different clinical sites in the US. Median patient age was 66 years (IQR: [54 years, 76 years]). 51.9% were female patients. Ethnicity was known for 290 cases (48.2%), out of which 66.2% were white, 26.9% were black or African American, 4.1% were hispanic and 2.8% were others. NIHSS score was known for 296 cases (49.2%) with median of 10 (IQR: [4,19]). Four different CT manufacturers were present in the data: Canon/Toshiba (40.4%), GE Medical Systems (16.3%), Philips (32.3%) and Siemens (11.0%).

Ground truth was established by two US-board certified neuroradiologists independently assessing the cases. In case of disagrement, adjudication was performed by a third US-board certified neuroradiologists. The data set contained 307 positive cases (with 134 occlusions in the ICA, 109 in the M1 segment and 64 in the M2 segment, respectively). The observed sensitivity and specificity with 95%-confidence intervals were 90.6% [86.8% - 93.3%] and 88.8% [84.7% – 91.9%], respectively, exceeding the predefined acceptance threshold of >80% sensitivity and specificity.

The performance results were consistent on all relevant subgroups including manufacturers, data origin, image quality ranges but also patient sex, age and ethnicity and different stroke symptom severity levels (measured by NIHSS).

In addition, the processing time was measured as the time elapsed between the completion of the data transfer to the application and the completion of writing of the results. Processing time was <110 seconds for all cases with a median of 42 seconds.

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.

Siemens hereby certifies that syngo.CT LVO Detection meets the following FDA Recognized Consensus standards listed below:

Standard	Version	Content	FDA Recognition Number (if applicable)
IEC 62304	62306 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes	13-79
NEMA PS 3.1 - 3.20 2022d	:2022	Digital Imaging and Communications in Medicine (DICOM) Set	12-349
ISO 14971	Third Edition 2019-12	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

Standard	Version	Content	FDA Recognition Number (if applicable)
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

9. Conclusion

syngo.CT LVO Detection 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 LVO Detection to be as safe, as effective and with performance substantially equivalent to the commercially available predicate device.