



September 25, 2026

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

Re: K260055

Trade/Device Name: syngo.CT Brain Quantification
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: August 27, 2026
Received: August 28, 2026

Dear Kenny 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260055

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Please provide the device trade name(s).

?

syngo.CT Brain Quantification

Please provide your Indications for Use below.

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syngo.CT Brain Quantification is a radiological post-processing application for the analysis of non-contrast head CT images. The device is intended for automatic labeling, visualization, and quantification of intracranial structures.

The software is indicated for use in the analysis of:

- Intracranial hyperdensities
- Midline Shift

The device is intended to be used in patients aged 18 years or above. No surgical signs must be present in the images.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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K260055

510(k) Summary

for

syngo.CT Brain Quantification with software version SOMARIS/8 VB80

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

1. Identification of the Submitter

Submitter

SIEMENS MEDICAL SOLUTIONS USA, INC.
810 INNOVATION DR.
KNOXVILLE, TN 37932
Registration Number: 1034973

Importer/Distributor

SIEMENS MEDICAL SOLUTIONS USA, INC.
40 Liberty Boulevard
Malvern, PA 19355
Registration Number: 2240869

Location of Manufacturing Site

Siemens Healthineers AG
SIEMENSSTRASSE 1 -OR-
Rittigfeld 1
FORCHHEIM Bavaria, DE 91301
Registration Number: 3004977335

Note: Descriptions in this submission use the short company name Siemens. It covers both manufacturing locations and names as listed above. Brand name on all products is Siemens Healthineers.

Submitter Contact Person:

Kenny M Bello
Regulatory Affairs Professional
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Molecular Imaging
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Knoxville, TN 37932
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2. Device Name and Classification

Product Name: *syngo*.CT Brain Quantification
 Propriety Trade Name: *syngo*.CT Brain Quantification
 Regulation Description: Medical Image Management and Processing System
 Classification Name: Automated Radiological Image Processing Software
 Classification Panel: Radiology
 CFR Section: 21 CFR §892.2050
 Device Class: Class II
 Product Code: QIH

3. Predicate Devices

Predicate Device:

Trade Name: qER-Quant
 Manufacturer: Qure.AI Technologies
 510(k) Number: K211222
 Clearance Date: 07/30/2021
 Regulation Description: Medical Image Management and Processing System
 Classification Name: Automated Radiological Image Processing Software
 Classification Panel: Radiology
 CFR Section: 21 CFR §892.2050
 Device Class: Class II
 Product Code: QIH

4. Device Description

syngo.CT Brain Quantification is a radiological post-processing application intended for the analysis of non-contrast head datasets acquired with computed tomography (CT) imaging systems. *syngo*.CT Brain Quantification is intended for automatic labeling, visualization, and quantification of intracranial structures. The subject device is intended to be used in the analysis of intracranial hyperdensities and in the quantification of the midline shift. The device receives images from a hosting system and returns DICOM images back to the hosting system, which can display the results within its user interface.

5. Indications for Use

syngo.CT Brain Quantification is a radiological post-processing application for the analysis of non-contrast head CT images. The device is intended for automatic labeling, visualization, and quantification of intracranial structures.

The software is indicated for use in the analysis of:

- Intracranial Hyperdensities
- Midline Shift

The device is intended to be used in patients aged 18 years or above. No surgical signs must be present in the images.

6. Indications for Use Comparison to the Predicate Device

Subject Device	Predicate Device
Siemens <i>syngo</i> .CT Brain Quantification	Qure.AI Technologies qER-Quant
syngo.CT Brain Quantification is a radiological post-processing application for the analysis of non-contrast head CT images. The device is intended for automatic labeling, visualization, and quantification of intracranial structures. The software is indicated for use in the analysis of: • Intracranial Hyperdensities • Midline Shift The device is intended to be used in patients aged 18 years or above. No surgical signs must be present in the images.	The qER-Quant device is intended for automatic labeling, visualization and quantification of segmentable brain structures from a set of Non-Contrast head CT (NCCT) images. The software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on NCCT images. qER-Quant provides volumes from NCCT images acquired at a single time point and provides a table with comparative analysis for two or more images that were acquired on the same scanner with the same image acquisition protocol for the same individual at multiple time points. The qER-Quant software is indicated for use in the analysis of the following structures: Intracranial Hyperdensities, Lateral Ventricles and Midline Shift.

Both devices share the same fundamental intended use: post-processing of non-contrast head CT images for automatic labeling, visualization, and quantification of brain structures.

Both devices are:

- Standalone post-processing software applications
- Using non-contrast head CT images as input
- Intended for automatic labeling, visualization and quantification of brain structures
- Indicated for use in the analysis of intracranial hyperdensities and midline shift

7. 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
	<i>syngo</i> .CT Brain Quantification	Qure.AI qER-Quant	
Regulation	21 CFR 892.2050	21 CFR 892.2050	Same
Product Code	QIH	QIH	Same
Regulation Description	Medical Image Management and Processing System	Medical Image Management and Processing System	Same
Device type	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	Same
Intended User	Hospital networks and qualified clinicians	Hospital networks and qualified clinicians	Same
Input images	Non-contrast CT	Non-contrast CT	Same
Body Part	Head	Head	Same
Target structures analyzed on NCCT scans	Intracranial hyperdensities and midline shift	Intracranial hyperdensities, lateral ventricles and midline shift	Similar Lateral ventricles are not target structures for <i>syngo</i> .CT Brain Quantification
Support of data acquired at multiple time points	No	Yes	Different Subject device operates on data acquired at single time point and does not provide functionality for analysis of images acquired at multiple timepoints.
Artificial Intelligence algorithm	Segmentation by deep learning (supervised voxel classification with Convolutional Neural Networks)	Segmentation by deep learning (supervised voxel classification with Convolutional Neural Networks)	Same

Feature	Subject Device	Predicate Device	Comparison Table
	syngo.CT Brain Quantification	Qure.AI qER-Quant	
Segmentation by deep learning (supervised voxel classification with Convolutional Neural Networks)	Yes	Yes	Same
Limited to analysis of imaging data	Yes	Yes	Same
Scanner Manufacturer of Input Data	Multi-vendor	Multi-vendor	Same
Output	Annotated DICOM Images with volumetric information of brain structures and midline shift	- Annotated DICOM Images with volumetric information of structures and midline shift - Multiple electronic reports (PDF)	Similar The subject device offers annotated DICOM images only without producing additional PDF reports.
Communication	DICOM Compatible	DICOM Compatible	Same
Reference Standard for Performance testing	<u>Accuracy</u> Manual labeled images for all structures	<u>Accuracy</u> Manually labeled images for all structures <u>Reproducibility</u> Test-retest images	Similar The subject device provides tests for accuracy.
Deployment	SOMARIS-X platform, syngo.via platform	Proprietary qure.AI Platform	Similar The predicate device operates on its proprietary platform while the subject device operates on the syngo compatible host systems SOMARIS-X and syngo.via since this device is a part of the Siemens application universe.

8. Performance Data

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

Software Verification and Validation

Software documentation at an Enhanced Documentation level per FDA's Guidance Document "Content of Premarket Submissions for Software Contained in Medical Devices" issued on June 14, 2023 is included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. 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.

Non-Clinical Testing Summary

Non-clinical testing submitted in support of substantial equivalence included software verification and validation testing, algorithm performance testing, cybersecurity testing, system integration testing, and risk management activities. Testing was conducted to verify that the device performs as intended and meets predefined acceptance criteria. All non-clinical test results supported the substantial equivalence of the device.

Clinical Testing Summary

Clinical performance of the device was evaluated in a retrospective, stand-alone study using anonymized non-contrast head CT datasets collected from multiple clinical institutions in the United States and Europe. The study assessed the performance of the Midline Shift Quantification module and the Brain Hyperdensity Segmentation module by comparison to ground-truth measurements established by experienced board-certified neuroradiologists.

The Midline Shift Quantification module was evaluated using 300 head CT cases to assess the accuracy of automated midline shift measurements. The data contains patients from 18 to 93 years of age (average 61.1 +/-19.4 years) with 51% males and 42% females and an average ground-truth midline shift of 2.4 +/-2.6 mm.

The Brain Hyperdensity Segmentation module was evaluated using 200 head CT cases containing acute intracranial hyperdensities. Algorithm-generated segmentation and volume measurements were compared to expert-generated ground-truth segmentations. Performance was assessed using volumetric accuracy and Dice Similarity Coefficient (DSC). The data contains patients from 18 to 98 years of age (average 62.4 +/-19.3 years) with 47% males and 40% females and an average ground-truth hyperdensity volume of 21.4 +/- 33.4 ml.

The clinical study demonstrated that the device met all predefined acceptance criteria.

Structure (Number of Series)	Absolute measurement difference		Dice Similarity Coefficient
	Mean (standard deviation)	Median (10 th -90 th percentile)	Mean (95% confidence interval)
Intracranial hyperdensities (200)	4.84 (6.85) ml	2.32 (0.16-12.60) ml	0.72 (0.68, 0.75)
Midline shift (300)	0.87 (1.04) mm	0.65 (0.16-1.78) mm	Not applicable

In addition, subgroup performance analyses were performed across relevant patient demographics (i.e., age, gender, origin), technical acquisition parameters (i.e., scanner manufacturer, model, slice thickness, kernel, etc.), clinical aspects (i.e. location, volume, confounders), and image quality parameters to demonstrate that algorithm performance is consistent across the intended-use population. Additionally, truthter variability analyses and linear regression analyses were conducted.

Conclusion from non-clinical and clinical tests

The non-clinical testing submitted in support of substantial equivalence demonstrated that the device meets its design specifications and performs as intended under the specified conditions of use. Software verification and validation activities, performance testing, cybersecurity testing, and other applicable non-clinical evaluations provided evidence that the device is safe and effective for its intended use.

Clinical testing demonstrated that the subject device can perform effective labeling, visualization, and quantification of intracranial hyperdensities and midline shift.

Collectively, the non-clinical and clinical test results support the conclusion that the subject device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness. Therefore, the data support a determination of substantial equivalence.

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.

Standards

Siemens hereby certifies that *syngo*.CT Brain Quantification meets the following FDA Recognized Consensus standards listed below:

Standard	Version	Content	FDA Recognition Number (if applicable)
IEC 62304	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	13-79
NEMA PS 3.1 - 3.20 2023e	2023	Digital Imaging and Communications in Medicine (DICOM) Set	12-352
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
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 Brain Quantification 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 Quantification to be as safe, as effective and with performance substantially equivalent to the commercially available predicate device.