June 25, 2026

Siemens Medical Solutions USA, Inc.
% Kenny M Bello
Regulatory Affairs Professional
810 Innovation Dr.
KNOXVILLE, TN 37932

Re: K253786
Trade/Device Name: syngo.CT Coronary Cockpit
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 22, 2026
Received: May 26, 2026

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic 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)*
K253786

Device Name
syngo.CT Coronary Cockpit

Indications for Use *(Describe)*
syngo.CT Coronary Cockpit is an image analysis software package for evaluating cardiac CT angiography volume data sets. Combining automated and semi-automated image processing, visualization and reporting tools, the software package is designed to assist the physician in confirming the presence or absence of coronary lesions and their evaluation, documentation, follow-up as well as treatment planning.

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.

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510(k) Summary

syngo.CT Coronary Cockpit (VC10)

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	Alaine Medio Regulatory Affairs Manager alaine.medio@siemens-healthineers.com +1 (865)206-0337
Submitter Address	SIEMENS MEDICAL SOLUTIONS USA, INC. 810 INNOVATION DR. KNOXVILLE, TN 37932 Registration Number: 1034973
Location of Manufacturing Site	Siemens Healthineers AG SIEMENSSTRASSE 1 -OR- Rittigfeld 1 FORCHHEIM Bavaria, DE 91301 Registration Number: 3004977335
Importer/Distributor	SIEMENS MEDICAL SOLUTIONS USA, INC. 40 Liberty Boulevard Malvern, PA 19355 Registration Number: 2240869

2. Device Name and Classification

Product Name:	*syngo*.CT Coronary Cockpit
Propriety Trade Name:	*syngo*.CT Coronary Cockpit
Classification Name:	Medical image management and processing system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	QIH

3. Predicate Devices

Predicate Device	
Trade Name:	Cleerly Labs v2.0
Classification Name:	Medical image management and processing system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ
K-Number:	K202280

Reference Device #1:

Trade Name:	*syngo*.CT Coronary Analysis
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
K-Number:	K173637

Reference Device #2:

Trade Name:	Philips Comprehensive Cardiac Analysis (CCA) – Plaque Assessment Tool
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK
K-Number:	K092747

4. Device Description

The medical device, syngo.CT Coronary Cockpit, is a software application, which is intended to be used as an interactive tool for viewing and analyzing coronary computed tomography angiography (CCTA) datasets. It is applied on the images acquired during the regular work-up and provides postprocessing and visualization functionalities for the evaluation of coronary artery disease. syngo.CT Coronary Cockpit VC10 is available as an extension for the MM Reading application on syngo.via. The syngo.CT Coronary Cockpit is an extension to One-Viewer based applications, i.e., it is not a standalone application but a plug-in to the hosting environment.

5. Indications for Use

syngo.CT Coronary Cockpit is an image analysis software package for evaluating cardiac CT angiography volume data sets. Combining automated and semi-automated image processing, visualization and reporting tools, the software package is designed to assist the physician in confirming the presence or absence of coronary lesions and their evaluation, documentation, follow-up as well as treatment planning.

6. Indications for Use Comparison to the Predicate Device

Subject Device syngo.CT Coronary Cockpit *(SOMARIS/8 VC10)*	Predicate Device Cleerly Labs v2
syngo.CT Coronary Cockpit is an image analysis software package for evaluating cardiac CT angiography volume data sets. Combining automated and semi-automated image processing, visualization and reporting tools, the software package is designed to assist the physician in confirming the presence or absence of coronary lesions and their evaluation, documentation, follow-up as well as treatment planning.	Cleerly Labs is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e. atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post processes CT images obtained using any Computed Tomography (CT) scanner. The software provides tools for the measurement and visualization of coronary arteries. The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations. Users should be aware that certain views make use of interpolated data. This is data that is created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

The syngo.CT Coronary Cockpit and Cleerly Labs v2 software applications are intended to assist physicians in the evaluation of cardiac computed tomography (CT) angiography datasets. These applications provide functionality for image processing, visualization, quantitative assessment, and reporting to support physicians in confirming the presence or absence of coronary artery lesions. Both devices provide an assessment of stenosis and coronary plaques, which in the case of syngo.CT Coronary Cockpit is reflected by the term "coronary lesions and their evaluation". The indication for treatment planning in syngo.CT Coronary Cockpit is not present in the predicate device.

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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:

Functionality		Subject Device	Predicate Device	Comparison Result
		syngo.CT Coronary Cockpit (SOMARIS/8 VC10)	Cleerly Labs v2.0	
Basic Visualization				
	2D image display	yes	yes	Comparable
	3D image display	yes	yes	Comparable
	Vessel display: CPR, cross-sections	yes	yes	Comparable
	Profile curve	yes	no	Comparable to reference device #1 *syngo.CT Coronary Analysis*
Vessel Definition and Visualization				
	Automatic Centerline Tracing	yes	yes	Comparable
	Centerline Editing	Yes	yes	Comparable
	Coronary Unfolded Vessel View visualization	yes	no	Comparable to Globe View feature of reference device #2 *Philips CT Comprehensive Cardiac Analysis*
Anatomical Evaluation				
	Lumen Segmentation Algorithm	yes	yes	Comparable
	Lumen Segmentation Display and Editing	yes	yes	Comparable
	Definition and Evaluation of lesions	yes	yes	Comparable
Plaque Evaluation				
	Vessel Wall Segmentation Algorithm	yes	yes	Comparable
	Vessel Wall Segmentation Display and Editing	yes	yes	Comparable

Functionality		Subject Device	Predicate Device	Comparison Result
		syngo.CT Coronary Cockpit (SOMARIS/8 VC10)	Cleerly Labs v2.0	
	Plaque Classification and Display	yes	yes	Comparable
	Plaque Quantification	yes	yes	Comparable
	Remodeling Index	yes	yes	Comparable
Stent Landing Zone Evaluation				
	Definition and Evaluation of Stent Landing Zone Markers	yes	No	Comparable to definition of stenosis markers in reference device #1 *syngo.CT Coronary Analysis*
	Export to Angio System as DICOM SSO	yes	No	Comparable to SSO Export in reference device #1 *syngo.CT Coronary Analysis*
General				
	Results creation and Reporting	Yes	Yes	Comparable
	Integration with Spectral Imaging	Yes	No	Comparable to spectral imaging support in reference device #1 *syngo.CT Coronary Analysis*

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

The coronary vessel tracing algorithm has been validated on 425 CT data sets from individual subjects. Data originated from 5 different US states and 3 different European countries. Data covers a mix of slice thicknesses from 0.2 to 1.0 mm and tube voltage from 70 KVP to 140 KVP. The coronary lumen and wall segmentation algorithms have been evaluated using a random subset of 150 cases of the above data. Additional details about the data distribution are shown below.

Category	Property	Count Vessel Tracing	Count Lumen and Wall segmentation
Manufacturer	Canon/Toshiba	72	23
	GE Med Sys	67	25
	Philips	61	27
	Siemens	225	75
Patient Sex	F	159	49
	M	264	101
	other / unknown	2	
Patient Age	22-49	65	13
	50-59	103	30
	60-69	144	60
	70-79	90	36
	≥80	22	10
	unknown	1	1
CAD-RADS score according to clinical report	0	90	8
	1	58	24
	2	64	26
	3	61	30
	4A	62	27
	4B	47	20
	5	43	15

For coronary vessel tracing, data was annotated by an ARRT-certified technologist with >15 years of experience and reviewed by a US-board certified radiologist (SCCT-Level 3 equivalent experience) or a US-board certified cardiologist (CBCC-Level 3 certification), both having >20 years of experience.

For coronary lumen and wall segmentation, two independent annotations were generated by a team of seven US-board certified radiologists or cardiologists with SCCT Level III or equivalent certification (years of experience ≥ 5, average 8.0 years). Adjudication was performed by a team of 2 US-board certified cardiologists with SCCT Level III or equivalent certification (7 and 25 years of experience, respectively).

For vessel tracing, the algorithm failed in 0% of the cases. Pointwise sensitivity and precision to identify vessels ≥ 1.5 mm were found to be 95.8% and 96.1%, respectively, with an average DICE of 95.7%.

For lumen segmentation, the algorithm failed in 0% of the cases. For coronary lumen segmentation, the following results were obtained:

Metric	Pearson's r
Lumen volume (normalized by vessel length)	0.906
Lumen diameters	0.861
Lumen area	0.859
Stenosis grading (diameter-based)	0.728
Stenosis grading (area-based)	0.755

For plaque localization, 94.8% of the ground truth plaque volume was part of a plaque cluster detected by the algorithm. Vice versa, 96.4% of the plaque volume calculated by the algorithm was part of a ground truth plaque cluster.

For plaque quantification the following results were obtained:

Metric	Pearson's r
Plaque volume (cluster-based)	0.883
Plaque volume (vessel-based)	0.883
Calcified	0.951
Non-calcified	0.727
High density	0.730
Low density	0.582
Remodeling index (lesion-based)	0.671

For all algorithms, consistent results were observed for all relevant subgroups. In summary, all performance targets were met.

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 Coronary Cockpit meets the following FDA Recognized Consensus standards listed below:

Standard	Version	Content	FDA Recognition Number (if applicable)
IEC 62304:2006 +AMD1:2015 (Ed.1.1)	:2015	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes	13-79
NEMA PS 3.1 - 3.20 2024e	:2024	Digital Imaging and Communications in Medicine (DICOM) Set	12-363
ISO 14971	:2019	Application of Risk Management to Medical Devices	5-125
IEC 62366-1	Edition 1.1 2020-06	Medical devices - Part 1: Application of usability engineering to medical devices	5-129

Standard	Version	Content	FDA Recognition Number (if applicable)
	CONSOLIDATED VERSION		
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. Predetermined Change Control Plan (PCCP)

Syngo.CT Coronary Cockpit has a Predetermined Change Control Plan (PCCP) authorized by FDA. The plan allows for the following modification of the lumen and wall segmentation algorithm:

- including additional training data,
- modification of hyper-parameters for algorithm training, and
- modification of pre- and post-processing parameters of the algorithm.

Any modified algorithm will undergo performance testing and software verification and validation described in Section 8. Only if both, performance testing and verification and validation, have been successfully passed, the modification will be implemented into the next suitable software version.

Users will be informed about updates, including modifications implemented under the authorized Predetermined Change Control Plan (PCCP), through multiple established communication mechanisms to ensure transparency and traceability. Specifically, users are informed through:

- Release notes provided with each software version, describing the implemented modifications, including PCCP-authorized changes and their impact on device performance where applicable;
- Updates to the Instructions for Use (IFU) and user documentation, reflecting relevant modifications and revised performance information;
- Direct customer communication by Siemens Healthineers Customer Service (CS) in connection with deployment activities, including information on the update content and version installed;
- Standard marketing and customer communication channels, as defined in the Siemens Healthineers Quality Management System (QMS), ensuring consistent dissemination of update-related information.

Through these combined measures, users are systematically informed of PCCP-authorized modifications and the corresponding software version in which they are implemented.

10. Conclusion

syngo.CT Coronary Analysis has the same intended use and similar indication for use as the predicate device. The subject device syngo.CT Coronary Analysis does not have changes in fundamental scientific technology compared to the predicate device. The technological characteristics are the same as the predicate device. For the subject device, syngo.CT Coronary Analysis, Siemens used the same testing with the same workflows as used to clear the predicate device. Siemens considers syngo.CT Coronary Cockpit to be as safe, as effective, and with performance substantially equivalent to the commercially available predicate device.