October 24, 2025

Siemens Healthineers AG
Vijay Ramadas
Regulatory Affairs Manager
Siemensstraße 3
Forchheim, Bayern 91301
Germany

Re: K251059
Trade/Device Name: Syngo Carbon Clinicals (VA41)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 18, 2025
Received: September 18, 2025

Dear Vijay Ramadas:

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
Assistant Director
Imaging Software Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251059

Device Name
Syngo Carbon Clinicals (VA41)

Indications for Use *(Describe)*
Syngo Carbon Clinicals is intended to provide advanced visualization tools to prepare and process the medical image for evaluation, manipulation and communication of clinical data that was acquired by the medical imaging modalities (for example, CT, MR, etc.)

OrthoMatic Spine provides the means to perform musculoskeletal measurements of the whole spine, in particular spine curve angle measurements.

The TimeLens provides the means to compare a region of interest between multiple time points.

The software package is designed to support technicians and physicians in qualitative and quantitative measurements and in the analysis of clinical data that was acquired by medical imaging modalities.

An interface shall enable the connection between the Syngo Carbon Clinicals software package and the interconnected software solution for viewing, manipulation, communication, and storage of medical images.

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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K251059

18-September-2025

510(k) Summary

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

1. **Submitter:**

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2. **Contact Person:**

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3. **Device Name and Classification**

Device/Trade Name:	Syngo Carbon Clinicals
Classification Panel:	Radiology Devices
Classification Number:	21 CFR 892.2050
Classification Name:	Medical Image Management and Processing System
Device Class:	Class II
Product Code:	QIH

4. **Predicate Device(s):**

Main Predicate Device

Device/Trade Name:	Syngo Carbon Clinicals
510(k) Clearance:	K232856
Classification Panel:	Radiology Devices
Classification Number:	21 CFR 892.2050
Classification Name:	Medical Image Management and Processing System
Device Class:	Class II
Product Code:	QIH

5. Device Description:

Syngo Carbon Clinicals is a software only Medical Device, which provides dedicated advanced imaging tools for diagnostic reading. These tools can be called up using standard interfaces any native/syngo based viewing applications (hosting applications) that is part of the SYNGO medical device portfolio. These tools help prepare and process the medical image for evaluation, manipulation and communication of clinical data that was acquired by medical imaging modalities (e.g., MR, CT etc.)

Deployment Scenario: Syngo Carbon Clinicals is a plug-in that can be added to any SYNGO based hosting applications (for example: Syngo Carbon Space, syngo.via etc…). The hosting application (native/syngo Platform-based software) is not described within this 510k submission. The hosting device decides which tools are used from Syngo Carbon Clinicals. The hosting device does not need to host all tools from the Syngo Carbon Clinicals, a desired subset of the provided tools can be used. The same can be enabled or disabled thru licenses.

When preparing the radiologist's reading workflow on a dedicated workplace or workstation, Syngo Carbon Clinicals can be called to generate additional results or renderings according to the user needs using the tools available.

6. Intended/Indications for use:

Syngo Carbon Clinicals is intended to provide advanced visualization tools to prepare and process the medical image for evaluation, manipulation and communication of clinical data that was acquired by the medical imaging modalities (for example, CT, MR, etc.)

OrthoMatic Spine provides the means to perform musculoskeletal measurements of the whole spine, in particular spine curve angle measurements.

The TimeLens provides the means to compare a region of interest between multiple time points.

The software package is designed to support technicians and physicians in qualitative and quantitative measurements and in the analysis of clinical data that was acquired by medical imaging modalities.

An interface shall enable the connection between the Syngo Carbon Clinicals software package and the interconnected software solution for viewing, manipulation, communication, and storage of medical images.

7. Technological Characteristics:

The Syngo Carbon Clinicals plug-in provides the below listed tools.

- **Cinematic insight –** An advanced visualization tool for cinematic rendering of anatomical structures using presets
- **Manual Calibration –** The Calibration tool is used manually calibrate non-calibrated images to enable measurement on such images
- **Basic Onco Tools**
  - **Assisted Perpendicular –** Tool to draw perpendicular distance lines to perform diameter measurements and thus to evaluate lesions
  - **Lesion Quantification –** Tool to perform diameter measurements (longest diameter, perpendicular diameter) and to create segmentation objects of suspect lesions in lung parenchyma with one click (semi automatically)
  - **Lung Nodule Marker –** Tool used to evaluate lung parenchyma for suspect lesions. This tool can also be used to evaluate lesions across different time points
- **OrthoMatic Spine** – An interactive tool that provides automated calculation of spine measurements in CR and DX images of the entire spine in Frontal and Lateral acquisition
- **Time Lens** – A tool that compares a region of interest between multiple timepoints

8. Summary of Differences between the Subject Device and the Predicate Device:

The differences between the subject device described in this premarket notification and the predicate device are summarized in the following comparison table:

Specification	Subject Device	Predicate Device	Comparison
Device name and version	Syngo Carbon Clinicals (VA41) K251059	Syngo Carbon Clinicals (VA30) K232856	New version of the predicate device with added features
Indications for use	Syngo Carbon Clinicals is intended to provide advanced visualization tools to prepare and process the medical image for evaluation, manipulation and communication of clinical data that was acquired by the medical imaging modalities (for example, CT, MR, etc.) OrthoMatic Spine provides the means to perform musculoskeletal measurements of the whole spine, in particular spine curve angle measurements. The TimeLens provides the means to compare a region of interest between multiple time points. The software package is designed to support technicians and physicians in qualitative and quantitative measurements and in the analysis of clinical data that was acquired by medical imaging modalities. An interface shall enable the connection between the Syngo Carbon Clinicals software package and the interconnected software solution for viewing, manipulation, communication, and storage of medical images.	Syngo Carbon Clinicals is intended to provide advanced visualization tools to prepare and process the medical image for evaluation, manipulation and communication of clinical data that was acquired by the medical imaging modalities (for example, CT, MR, etc.) The software package is designed to support technicians and physicians in qualitative and quantitative measurements and in the analysis of clinical data that was acquired by medical imaging modalities. An interface shall enable the connection between the Syngo Carbon Clinicals software package and the interconnected software solution for viewing, manipulation, communication, and storage of medical images.	Indications adapted to include the new features
Contraindications	Syngo Carbon Clinicals is not indicated for mammography images for diagnosis in the U.S. Syngo Carbon Clinicals is not to be used as a sole basis for clinical decisions	Syngo Carbon Clinicals is not indicated for mammography images for diagnosis in the U.S. Syngo Carbon Clinicals is not to be used as a sole basis for clinical decisions	Same

Specification	Subject Device	Predicate Device	Comparison
Software architecture	Syngo Carbon Clinicals has architecture that is based on a layered pattern where the various clinical tools/functionality are decomposed into modules/common tools which provide their individual functionalities.	Syngo Carbon Clinicals has architecture that is based on a layered pattern where the various clinical tools/functionality are decomposed into modules/common tools which provide their individual functionalities.	Same
Image communication	Syngo Carbon Clinicals relies on the interfacing application for Image communication.	Syngo Carbon Clinicals relies on the interfacing application for Image communication.	Same
Image display algorithms	• Rendering Tools: Cinematic Insight	• Rendering Tools: Cinematic Insight	Same
Measurement, Evaluation/Interpretation Tools	• Oncological evaluation: o Lesion Quantification o Assisted Perpendicular Tool o Lung Nodule Marker o **Time Lens** • Orthopaedic measurements: o Manual calibration o **OrthoMatic Spine**	• Oncological evaluation: o Lesion Quantification o Assisted Perpendicular Tool o Lung Nodule Marker • Orthopaedic measurements: o Manual calibration	**Time Lens** tool enables comparison of a region of interest between multiple timepoints. **OrthoMatic Spine** tool provides automated calculation of spine measurements in CR and DX images.
Supported objects for display	DICOM image object display • CT Image • DX Image • CR Image	DICOM image object display • CT Image • DX Image • CR Image	Same

Specification	Subject Device	Predicate Device	Comparison
Operating system	None Syngo Carbon Clinicals relies on the interfacing application for operating system.	None Syngo Carbon Clinicals relies on the interfacing application for operating system.	Same
Impact on Image Acquisition Devices	None Syngo Carbon Clinicals provides advanced visualization tools to prepare and process the medical images and it has no influence on the image acquisition devices	None Syngo Carbon Clinicals provides advanced visualization tools to prepare and process the medical images and it has no influence on the image acquisition devices	Same
CAD Functionalities	None No automated diagnostic interpretation capabilities like CAD are included. All image data are to be interpreted by trained personnel.	None No automated diagnostic interpretation capabilities like CAD are included. All image data are to be interpreted by trained personnel.	Same
Clinical condition the device is intended to diagnose, treat, or manage	No limitation on the clinical condition of the patient	No limitation on the clinical condition of the patient	Same
Intended patient population	No limitation concerning the patient population (e.g., age, weight, health, condition)	No limitation concerning the patient population (e.g., age, weight, health, condition)	Same
Site of the body the device is intended to be used	No limitation concerning region of body or tissue type	No limitation concerning region of body or tissue type	Same
Intended use environment	Syngo Carbon Clinicals offers a wide range of tools from the major clinical fields, i.e. general radiology, oncology environments.	Syngo Carbon Clinicals offers a wide range of tools from the major clinical fields, i.e. general radiology, oncology environments.	Same
Intended user(s)	Trained healthcare professionals	Trained healthcare professionals	Same
Device Type	Software application	Software application	Same

Specification	Subject Device	Predicate Device	Comparison
Cyber Security	The cybersecurity aspects for Syngo Carbon Clinicals is handled by the interfacing/hosting system.	The cybersecurity aspects for Syngo Carbon Clinicals is handled by the interfacing/hosting system.	Same
Graphical user interface	Not offered by Syngo Carbon Clinicals, it relies on the hosting applications	Not offered by Syngo Carbon Clinicals, it relies on the hosting applications	Same
Image Archiving	Not offered by Syngo Carbon Clinicals	Not offered by Syngo Carbon Clinicals	Same
Annotation Tool	Not offered by Syngo Carbon Clinicals	Not offered by Syngo Carbon Clinicals	Same
Printing	Not offered by Syngo Carbon Clinicals	Not offered by Syngo Carbon Clinicals	Same
Online help system	Yes, with search, indexing, filtering, library function and document collections	Yes, with search, indexing, filtering, library function and document collections	Same

9. Clinical Testing

No clinical studies were carried out for the product, all performance testing was conducted in a non-clinical fashion as part of verification and validation activities of the medical device

10. Performance Evaluation Summary

Orthomatic Spine:

A. Summary Test Statistics and Acceptance Criteria

A reader study was performed utilizing 150 spine X-ray images (comprising 75 frontal and 75 lateral views) and included five US board-certified radiologists. The OrthoMatic Spine core algorithm's outputs for six primary spinal measurements—Cobb angles, coronal balance, kyphosis angle, lordosis angle, and sagittal vertical alignment—were assessed against the mean values obtained from the radiologists' assessments. Algorithm performance was evaluated using cumulative distribution functions (CDFs), which demonstrated that the algorithm's measurement deviations fell within the range of inter-reader variability for the major Cobb angle, thoracic kyphosis angle, lumbar lordosis angle, coronal balance, and sagittal vertical alignment. These findings indicate that the algorithm closely replicates average rater performance and satisfies the predetermined clinical reliability acceptance criteria.

B. Number of Individual Patients

The main dataset used for training includes 6,135 unique patients, with most undergoing one or two full-spine imaging exams.

C. Number of Samples and Relationship to Patients

A total of 23,464 images were collected, including multiple image types per patient (e.g., frontal, lateral, partial spine views).

D. Demographic Distribution

i. Gender: 56% Female, 36% Male, 8% Unknown.
ii. Age: Patients span from 5 to 85 years, with at least 200 images per 5-year interval.
iii. Geographic Location: Data collected from USA, Germany, Ukraine, Austria and Canada.

Note: *It is notable that young female patients are overrepresented in the study dataset*

E. Clinical Subgroups and Confounders

The dataset includes patients with various spinal conditions, notably adolescent idiopathic scoliosis. Confounders include variability in imaging protocols and equipment, differences in image quality, and images with and without pathologies.

F. Equipment and Protocols Used

Images were acquired using systems from a wide range of manufacturers, including Siemens Healthineers (38%), EOS imaging (17%), Agfa (16%), KODAK (11%), KONICA MINOLTA (8%), Canon Inc. (2%), GE Healthcare (2%), and others. This diversity supports the algorithm’s generalizability across imaging platforms.

G. Reference Standard Derivation (Truthing Process)

Most of the images were annotated using a dedicated annotation tool (Darwin, V7 Labs) by US-based medical data labeling company (Cogito Tech LLC). Initial annotations were performed by trained non-radiologists and reviewed by board-certified

radiologists. Annotations included vertebral landmarks and key vertebrae (C7, L1, S1). The process was guided by written guidelines and automated workflows to ensure quality and consistency.

H. Independence of Test Data from Training Data

The dataset was split into 60% for training, 20% for validation, and 20% for model selection. Splitting was done at the patient level, ensuring no overlap between subsets. Stratification ensured balanced representation across data sources and patient positions.

TimeLens:

There is no reader study/bench test that was required for the TimeLens tool as the AI algorithm is very simple workflow enhancement algorithm and the above criteria does not affect the algorithm.

11. Non-clinical Performance Testing:

Non-clinical tests were conducted for the subject device during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

Siemens Healthcare GmbH claims conformance to the following standards:

- ISO 14971 Third Edition 2019-12
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION
- IEC 82304-1 Edition 1.0 2016-10
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION

12. Software Verification and Validation:

Software documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on the device Syngo Carbon Clinicals during product development.

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 for the device was found acceptable to support the claims of substantial equivalence.

Siemens Healthcare GmbH conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Contained in this submission are our cybersecurity considerations as they relate to the device Syngo Carbon Clinicals.

13. Conclusion as to Substantial Equivalence:

The predicate device was cleared based on non-clinical supportive information. The comparison of technological characteristics, device hazards, non-clinical performance data, and software validation data demonstrates that the subject device performs comparably to and is as safe and effective as the predicate device that is currently marketed for the same intended use.

In summary, we are of the opinion that the subject device Syngo Carbon Clinicals, software version VA41, does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device Syngo Carbon Clinicals VA30.