Siemens Healthcare GmbH
Vijay Ramadas
Regulatory Affairs Manager
Siemensstraße 3
FORCHHEIM, BAYERN 91301
GERMANY

May 23, 2024

Re: K240294
Trade/Device Name: Syngo Carbon Enterprise Access (VA40A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: April 15, 2024
Received: April 15, 2024

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.

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
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.

Submission Number *(if known)*

K240294

Device Name

Syngo Carbon Enterprise Access (VA40A)

Indications for Use *(Describe)*

Syngo Carbon Enterprise Access is indicated for display and rendering of medical data within healthcare institutions

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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January 30, 2024

Traditional 510(k) Summary

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

1. **Submitter:**

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Germany

2. **Establishment Registration Number:**

3004977335

3. **Contact Person:**

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4. **Device Name and Classification**

Device/Trade Name:	Syngo Carbon Enterprise Access (VA40A)
Classification Panel:	Radiology Devices
Classification Number:	21 CFR 892.2050
Classification Name:	Medical Image Management and Processing System
Device Class:	Class II
Product Code:	LLZ

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

Device/Trade Name:	Syngo Carbon Space
510(k) Clearance:	K230561
Classification Panel:	Radiology Devices
Classification Number:	21 CFR 892.2050
Classification Name:	Medical Image Management and Processing System
Device Class:	Class II
Product Code:	LLZ

6. Device Description:

Syngo Carbon Enterprise Access is a software only medical device which is intended to be installed on recommended common IT Hardware. The hardware is not seen as part of the medical device. Syngo Carbon Enterprise Access is intended to be used in clinical image and result distribution for diagnostic purposes by trained medical professionals and provides standardized generic interfaces to connect to medical devices without controlling or altering their functions.

Syngo Carbon Enterprise Access provides an enterprise-wide web application for viewing DICOM, non-DICOM, multimedia data and clinical documents to facilitate image and result distribution.

7. Intended/Indications for use:

Syngo Carbon Enterprise Access is indicated for display and rendering of medical data within healthcare institutions.

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:

The predicate device is available in two variants;

- Syngo Carbon Space Diagnostic Workspace
- Syngo Carbon Space Physician Access (web component - this is the predicate for the subject device)

For readability and comparison purpose, the non-relevant items from the predicate device (contents of Syngo Carbon Space Diagnostic Workspace) are GREYED OUT and the relevant contents are retained

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Device name and version	Syngo Carbon Enterprise Access **VA40A**	Syngo Carbon Space VA30A (K230561)	New version of the product	NA
Manufacturer	Siemens Healthcare GmbH	Siemens Healthcare GmbH	Same	NA
Indications for use	Syngo Carbon Enterprise Access is indicated for display and rendering of medical data within healthcare institutions.	Syngo Carbon Space is a software intended to display medical data and to support the review and analysis of medical images by trained medical professionals. Syngo Carbon Space "Diagnostic Workspace" is indicated for display, rendering, post-processing of medical data (mostly medical images) within healthcare institutions, for example, in the field of Radiology, Nuclear Medicine and Cardiology. Syngo Carbon Space "Physician Access" is indicated for display and rendering of medical data within healthcare institutions.	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Contraindications	Syngo Carbon Enterprise Access is not intended for the diagnosis of digital mammography images and digital pathology reading. Syngo Carbon Enterprise Access is not intended to be used for diagnostic purpose on mobile devices in the United States of America (USA). Syngo Carbon Enterprise Access is not intended to be used as a sole basis for clinical decisions.	Syngo Carbon Space "Diagnostic Workspace" is not intended for diagnosis of digital mammography images. Syngo Carbon Space "Diagnostic Workspace" is not intended to be used as a sole basis for clinical decisions. Syngo Carbon Space "Physician Access" is not intended for diagnosis of digital mammography images. Syngo Carbon Space "Physician Access" is not intended to be used for diagnostic purpose on mobile devices in the United States of America (USA). Syngo Carbon Space "Physician Access" is not intended to be used as a sole basis for clinical decisions.	Same	NA
Software architecture	Syngo Carbon Enterprise Access is based on a client-server architecture	Syngo Carbon Space is based on a client-server architecture	Same	NA
Image communication	Standard network protocols like TCP/IP and standard communication protocol including DICOM (2016a) and non-DICOM objects.	Standard network protocols like TCP/IP and standard communication protocol including DICOM (2016a) and non-DICOM objects. Supports interfacing with HL7 (v2.5 / v2.3.1 / v2.3 / FHIR R4).	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Image display algorithms	• MPR: MPR • MIP: MIP, • MinIP View • AVG • MED • Invert Image	• MPR: MPR, MPR Thick, MPR/MPR* • MIP: MIP, MIP Thin • MinIP View • VRT*: Plain VRT, Adapt VRT, VRT Thin, Cinematic VRT • Fused View * • Invert Image * available in in Diagnostic Workspace only	The additional AVG and MED are non AI/ML Algorithms	This differences between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Measurement, Evaluation/Interpretation Tools	• Distance (Distance line) • Pixel Lens • Angle • Elipse Annotation • Polygon • Freehand • Capture	• Distance (Distance line, Distance Polyline) • Angle and **Angle on stack*** • 2D ROI (Circle, Freehand, Polygonal, Auto Contour) * • 3D VOI (Sphere, Freehand) * • Pixel Lens • Ranges (Parallel, Radial, Radial Sliced, Curved, Spine) * • Lesion Quantification* • Assisted Perpendicular Tool* • Automatic Organ Segmentation* • Interactive Tissue Segmentation* • Time Curve, Time ROI* • SUV Measurement* • Automatic Anatomy Labeling (rib, spine) * • Next Study/Previous Study/**Nearline study*** • **Change Geometry*** • Snapshot • **CT Lung Change*** • **MR General Reading*** • **Alpha Blending*** * Available in in Diagnostic Workspace only	The tool set in the subject device is enhanced.	This differences between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken

Supported objects for display	DICOM image object display: • CR Image • CT Image • DX Image • ES Image • GM Image • MG Image • MR Image • NM Image • PET Image • OP/OPT Image • RF Image • RT IMAGE • SM (WSI) • XA Image • US Image • Secondary capture objects DICOM non-image object display: • ECG • Encapsulated PDF • PR Non-DICOM file display: • Images: BMP, GIF, JPEG (JFIF), JPEG 2000, JPEG-LE, JPEG-LS, PCX, PNG, PNM, TIFF, WBMP • Video: FLV, H.264, H.265, INDEO2, INDEO3, INDEO4, MPEG1, MPEG2, MPEG4,	DICOM image object display: • CR Image • CT Image • DX Image • ES Image • GM Image • MG Image • MR Image • NM Image • PET Image • OP/OPT Image • RF Image • RT IMAGE • SM (WSI) • XA Image • US Image • Secondary capture objects DICOM non-image object display: • ECG • Encapsulated PDF • PR Non-DICOM file display: • Images: BMP, GIF, JPEG (JFIF), JPEG 2000, JPEG-LE, JPEG-LS, PCX, PNG, PNM, TIFF, WBMP • Video: FLV, H.264, H.265, INDEO2, INDEO3, INDEO4, MPEG1, MPEG2, MPEG4,	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
	VP8, VP9, WMV1, WMV2, WMV3 Text Documents: CDA (XML), PDF	VP8, VP9, WMV1, WMV2, WMV3 • Text Documents: CDA (XML), PDF		

Operating system	Server • Red Hat Enterprise Linux 9.x Client All operating systems that with support for the following HTML5- and JavaScript enabled browsers: • Google Chrome ≥ 90 • Microsoft Edge ≥ 90 • Mozilla Firefox ≥ 91 • Mozilla Firefox ESR ≥ 91 • Apple Safari ≥ 15 Mobile device iPadOS ≥ 16 Apple Safari web browser >= 15	Diagnostic Workspace Server • Microsoft Windows Server 2019 • Windows 10 Enterprise • Red Hat Enterprise Linux 8.4 Client • Microsoft Windows 10 (Pro, Pro-Education, Enterprise) • **Microsoft Windows 11 (Pro, Pro-Education, Enterprise)** Physician Access Server • Red Hat Enterprise Linux 8.4 Client All operating systems that with support for the following HTML5- and JavaScript enabled browsers: • Google Chrome ≥ 90 (tested and recommended Chrome 100) • Microsoft Edge ≥ 90 (tested and recommended: Edge 100) • Mozilla Firefox ≥ 91 • Mozilla Firefox ESR ≥ 91 • Apple Safari ≥ 14	The operating system for Linux, iOS and Safari browser version is updated	This Operating System and browser version difference between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as necessary measures have been taken

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
		Client – Mobile device iPadOS ≥ 14, Safari web browser		
Impact on Image Acquisition Devices	None Syngo Carbon Enterprise Access is a pure viewing software and it has no influence on the image acquisition devices.	None Syngo Carbon Space is a pure viewing and/or post-processing software and it has no influence on the image acquisition devices.	Same	NA
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	NA
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	NA
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	NA
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	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Intended use environment	Syngo Carbon Enterprise Access is used in departmental environments within healthcare institutions. For reading images certified monitors are required (e.g., medical diagnostic displays).	Syngo Carbon Space “Diagnostic Workspace” is used in Radiology, Nuclear Medicine and Cardiology environments (e.g., darkened/ shaded rooms). Syngo Carbon Space "Physician Access" is used in departmental environments within healthcare institutions. For reading images certified monitors are required (e.g., medical diagnostic displays).	Same	NA
Intended user(s)	Trained healthcare professionals	Trained healthcare professionals	Same	NA
Device Type	Software application	Software application	Same	NA
Software architecture	Syngo Carbon Enterprise Access is based on a client-server architecture	Syngo Carbon Space is based on a client-server architecture	Same	NA
Software self-test / checks	N/A – this is a browser based application	Client installation is prevented automatically in case if the system doesn’t have the recommended operating system. Also during the launch of the client every time, the compatibility to the server version is checked and request to update/upgrade to client in case of mismatch.	NA	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Cyber Security	• User access control • Audit Trail • Documentation of system security information, Network traffic & Firewall control • Support of virus / malware protection • System Hardening (OS level and Network level)	• User access control • Audit Trail • Documentation of system security information, Network traffic & Firewall control • Support of virus / malware protection • System Hardening (OS level and Network level)	Same	NA
Hardware	Hardware is not understood as part of the medical device but needs to comply with the minimum requirements as specified by Syngo Carbon Enterprise Access	Hardware is not understood as part of the medical device but needs to comply with the minimum requirements as specified by Syngo Carbon Space.	Same	NA
Graphical user interface	Yes, with reduced color palette, clearer structure, and text labels on icons. Floating panels increases the user friendliness as the user can move the panels wherever they are convenient with.	Yes, with reduced color palette, clearer structure, and text labels on icons. Floating panels increases the user friendliness as the user can move the panels wherever they are convenient with.	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Patient Browser	• Search, browse & open data for display from syngo.share core & remote DICOM nodes • Search, browse & open data for display from external XDS(-I) repository) • Archive functionality (upload medical data to syngo.share core for archive) • Document properties functions (metadata modification and tagging) • Correct & re-arrange functions • Restore (trigger fetch from archive) functions • Distribution, export & sharing functions • Inbox - access to medical data shared by other users	• Search, browse & open data for display from syngo.share core & remote DICOM nodes • Search, browse & open data for display from external XDS(-I) repository) ** • Archive functionality (upload medical data to syngo.share core for archive) • Document properties functions (metadata modification and tagging) • Correct & re-arrange functions • Restore (trigger fetch from archive) functions • Distribution, export & sharing functions • Inbox - access to medical data shared by other users ** **available in Physician Access only	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Series navigator / Document Preview	Yes, with a fast overview of the displayed and not displayed data (series, images) of the loaded studies, quickly identify the relevant series/images for reading, and bring data (timepoints/series/images) into display in an efficient manner (Drag&Drop). Study / Timepoints are marked with individual colors for better identification.	Yes, with a fast overview of the displayed and not displayed data (series, images) of the loaded studies, identify not yet seen series/images*, quickly identify the relevant series/images for reading, and bring data (timepoints/series/images) into display in an efficient manner (Drag&Drop). Study / Timepoints are marked with individual colors for better identification. The Series Navigator is called Document Preview for Physician Access. * available in in Diagnostic Workspace only	Same	NA
Findings panel	Findings panel collects measurements, annotations, and graphical objects. Additionally, the user can create new findings, edit findings. It also allows creation of automatic findings.	Findings panel collects measurements, annotations, and graphical objects. Additionally, the user can create new findings, edit findings. It also allows creation of automatic findings.	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Reporting	No dedicated report creation functionality supported in Syngo Carbon Enterprise Access	No dedicated report creation functionality supported in Syngo Carbon Space. Structured findings can be automatically transferred to external third-party reporting system via FHIR interface for creation of structured report content [e.g. (Powerscribe [by Nuance], SmartReports [by Smart Reporting)]	Same	NA
Image Archiving	Not applicable since Syngo Carbon Enterprise Access does not create data or images that is transferred/stored.	Diagnostic Workspace: Syngo Carbon Space Diagnostic Workspace does not store data or images. Created results for a study (e.g. DICOM PR, SR objects) are stored in syngo.share core in context of the original study. syngo.share core is responsible for long term archiving of the original study and created results. Physician Access: Not applicable since Syngo Carbon Space Physician Access does not create data or images that is transferred/stored.	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Patient Jacket	Provides access to patient history – other studies of patient stored in remote DICOM nodes. Also provides a study content preview along with access to nearline studies and prior RIS reports	Provides access to patient history – other studies of patient stored in syngo.share core or remote DICOM nodes. Also provides a study content preview Along with access to nearline studies and prior RIS reports	Same	NA
Optimization & preparation/ Spatial Operation tools	• Image Preview • Zoom/Pan • Synch, Align • Windowing • Flip (Horizontal, Vertical) • Blow-up • Scroll • Movie • Magnifier	• Image Preview • Zoom/Pan • Fit to Segment*, Fit to Acquisition Size* • Synch, Align • Windowing • Rotate (2D image or 3D Volume*) • Flip (Horizontal, Vertical) • Shutters On/Off* • Blow-up • Scroll • Movie • Clipping* • Punching and Masking* • Magnifier * available in in Diagnostic Workspace only	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Annotation Tool	• Text	• Arrow* • Marker* • Text * available in in Diagnostic Workspace only	Same	NA
Printing	Provides printing functionality on a paper printer.	Diagnostic workspace: Provides printing functionality with able to review, modify the images along with selecting the print sheet format exposing then the **DICOM printer.** Also, able to monitor the printing status and retry a printing task, if needed. *Note* *• DICOM printer must be configured as DICOM nodes* *• Grayscale & color printing is supported* Phyisican Access: Provides printing functionality on a paper printer.	Same	NA
Online help system	Yes, with search, indexing, filtering, library function and document collections.	Yes, with search, indexing, filtering, library function and document collections.	Same	NA

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. 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

11. Software Verification and Validation:

Basic documentation as 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 Enterprise Access 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 Enterprise Access.

12. Summary:

Performance tests were conducted to test the functionality of the device Syngo Carbon Enterprise Access. These tests have been performed to assess the functionality of the subject device. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.

13. Safety and Effectiveness Information:

Software specifications, design descriptions, hazard analysis, and labeling information are submitted in support of this premarket notification. The device labeling contains instructions for use with cautions to provide for safe and effective use of the device.

The results of the hazard analysis combined with the appropriate preventive measures taken indicate the device is of moderate level of concern, as per the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

14. 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 Enterprise Access, software version VA40A, does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device Syngo Carbon Space VA30A.