



Siemens Healthineers AG
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

September 29, 2026

Re: K263048

Trade/Device Name: Syngo Carbon Space (VA4)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 31, 2026
Received: August 31, 2026

Dear Prithul Bom:

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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA".

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.

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Please provide the device trade name(s).

?

Syngo Carbon Space (VA4)

Please provide your Indications for Use below.

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Syngo Carbon Space 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.

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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Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☐ Adults (22 years old and greater)

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29-September-2026

K263048 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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91301 Forchheim Germany

2. Establishment Registration Number:

3004977335

3. Contact Person:

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4. Device Name and Classification

Device/Trade Name: Syngo Carbon Space (VA4)

Classification Panel: Radiology Devices

Classification Number: 21 CFR 892.2050

Common Name: System, Image processing, Radiological Classification Name: Medical Image Management and

Processing System Device Class: Class II

Product Code: LLZ

5. Legally Marketed Predicate Device:

Device/Trade Name:	Syngo Carbon Space (VA30A) 510(k) Clearance: K230561	
Common Name:	System, Image processing, Radiological Classification Name:	Medical Image Management and
Processing System Classification Panel:	Radiology Devices	
CFR Section:	21 CFR §892.2050	
Device Class:	Class II	
Product Code:	LLZ	

6. Indications for Use:

Syngo Carbon Space 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.

7. Device Description:

Syngo Carbon Space 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 Space is intended to support reviews and analysis of medical images by trained medical practitioners. The software is used in Radiology for reading images and throughout the healthcare institutions for image & result distribution.

Syngo Carbon Space provides a reading workspace for Radiology that supports display of medical image data & documents and connects intelligent work tools (diagnostic and non-diagnostic software elements) to enable easy access to the data needed, easy access to external tools and creation of actionable results.

Since Syngo Carbon Space is a software only product, shelf-life is not applicable because of low likelihood of time-dependent product degradation. Hence performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period

Syngo Carbon Space is a software only medical device, which is delivered by download only option to be installed on common IT hardware. This hardware must fulfil the defined requirements. Any hardware platform that complies to the specified minimum hardware and software requirements and with successful installation verification and validation activities can be supported. The hardware itself is not seen as part of the medical device and therefore not in the scope of the 510(k) submission.

Syngo Carbon Space provides tools and features to cover the radiological tasks *reading images* and support *reporting* through third party tools. It supports DICOM and Non-DICOM objects. In a comprehensive imaging suite, Syngo Carbon Space interoperates with a Radiology Information System (RIS) to enable customer specific workflows.

Syngo Carbon Space is based on a client-server architecture. The server processes and renders the data from the connected modalities. The server provides central services including image processing and temporary storage. The client provides the user interface for interactive image viewing

and processing and can be installed and started on each workplace that has a network connection to the server.

Syngo Carbon Space supports various monitor setups and can be adapted to a range of image types by connecting different monitor types.

The subject device and the predicate device share the same fundamental scientific technology. This device description holds true for the subject device and the predicate device.

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

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

Note: The option “Physician Access” is carved out in the subject device and is marketed as a stand-alone device “Syngo Carbon Enterprise Access”. Hence, all items related to “Physician Access” is removed in the comparison below and the table compares only the Diagnostic Workspace option.

Specification	Subject Device	Predicate Device	Comparison
Device name and version	Syngo Carbon Space VA4	Syngo Carbon Space VA30A (K230561)	New version of the product
Indications for use	Syngo Carbon Space 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 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	Intended use was simplified and it still conveys the same indication The term “Diagnostic Workspace” is removed, as the subject device offers only one reader option The option “Physician Access” is carved out and not in scope of subject device

Specification	Subject Device	Predicate Device	Comparison
Contraindications	Syngo Carbon Space 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.	The subject device introduces Mammo Reading, hence removed Mammo related contraindication The term “Diagnostic Workspace” is removed, as the subject device offers only one reader option.
Software architecture	Syngo Carbon Space is based on a client-server architecture	Syngo Carbon Space is based on a client-server architecture	Same
Image communication	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).	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
Image display algorithms	• 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	• 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	Same

Specification	Subject Device	Predicate Device	Comparison
Measurement, Evaluation/Interpretation Tools	- 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 Mammography Reading Motion Correction	- 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	New tools were added to the subject device.

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
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Specification	Subject Device	Predicate Device	Comparison
	VP8, VP9, WMV1, WMV2, WMV3 Text Documents: CDA (XML), PDF	VP8, VP9, WMV1, WMV2, WMV3 Text Documents: CDA (XML), PDF	
Operating system	Server - Windows Server 2019, 2022, 2025 Client - Windows 10 (Pro, Pro-Education, Enterprise, LTSC) Windows 11 (Pro, Pro-Education, Enterprise)	Server - Microsoft Windows Server 2019 - Windows 10 Enterprise - Red Hat Enterprise Linux 8.4 Client - Microsoft Windows 10 (Pro, Pro-Education, Enterprise)	The subject device supports newer versions of Microsoft Windows OS in server and client.
Impact on 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.	None Syngo Carbon Space is a pure viewing and/or post-processing software 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

Specification	Subject Device	Predicate Device	Comparison
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 Space is used in Radiology, Nuclear Medicine and Cardiology environments (e.g., darkened/ shaded rooms).	Syngo Carbon Space “Diagnostic Workspace” is used in Radiology, Nuclear Medicine and Cardiology environments (e.g., darkened/ shaded rooms).	The term “Diagnostic Workspace” is removed, as the subject device offers only one reader option.
Intended user(s)	Trained healthcare professionals	Trained healthcare professionals	Same
Device Type	Software application	Software application	Same
Software architecture	Syngo Carbon Space is based on a client-server architecture	Syngo Carbon Space is based on a client-server architecture	Same
Software self-test / checks	Client installation is prevented automatically in case 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.	Client installation is prevented automatically in case 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.	Same

Specification	Subject Device	Predicate Device	Comparison
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
Hardware	Hardware is not understood as part of the medical device but needs to comply with the minimum requirements as specified by Syngo Carbon Space.	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
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

Specification	Subject Device	Predicate Device	Comparison
Patient Browser	• Search, browse & open data for display from syngo.share core & remote DICOM nodes • 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	• Search, browse & open data for display from syngo.share core & remote DICOM nodes • 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	Same
Series navigator / Document Preview	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.	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.	Same

Specification	Subject Device	Predicate Device	Comparison
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
Reporting	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])]	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
Image Archiving	Syngo Carbon Space does not store data or images.	Syngo Carbon Space Diagnostic Workspace does not store data or images.	Same

Specification	Subject Device	Predicate Device	Comparison
Patient Jacket	Provides access to patient history – other studies of patient stored in 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 DICOM nodes. Also provides a study content preview Along with access to nearline studies and prior RIS reports	Same
Optimization & preparation/ Spatial Operation tools	• 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	• 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	Same
Annotation Tool	• Arrow • Marker • Text	• Arrow • Marker • Text	Same

Specification	Subject Device	Predicate Device	Comparison
Printing	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. <i>Note</i> • DICOM printer must be configured as DICOM nodes • Grayscale & color printing is supported	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. <i>Note</i> • DICOM printer must be configured as DICOM nodes • Grayscale & color printing is supported	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. Bench Testing Evaluation Summary

The results of phantom and reader studies conducted on the Lesion Quantification Algorithm, in the predicate device, were evaluated for fit for use in the subject device and it was concluded that the Algorithm can be integrated in the subject device with few design mitigations to overcome the drawbacks/limitations specified in these studies. These design mitigations were validated by non-Clinical performance testing were found acceptable.

There are no changes to the algorithm and its performance that requires a new bench testing for the subject device. The results/summary from the predicate device is still applicable for the subject device.

11. Non-clinical Performance Testing:

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

Siemens claims conformance to the following standards:

- NEMA PS 3.1 - 3.20 2025d
- ISO 14971 Third Edition 2019-12
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
- IEC 82304-1 Edition 1.0 2016-10
- ANSI AAMI SW96:2023

12. Software Verification and Validation:

Software documentation at the level of “Basic Documentation” per FDA’s Guidance Document “Content of Premarket Submissions for Device Software Functions” 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 Space 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 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 Section B of this submission are our cybersecurity considerations as they relate to the device Syngo Carbon Space.

13. Summary:

Performance tests were conducted to test the functionality of the device Syngo Carbon Space. 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.

14. 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 Basic Documentation, as per the Guidance for the Content of Premarket Submissions for Device Software Functions

15. 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 Space, software version VA4, 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.