Siemens Healthcare GmbH
℅ Vijay Ramadas
Regulatory Affairs Manager
Siemensstr. 1
Forchheim, Baveria 91301
GERMANY

June 21, 2022

Re: K213665
Trade/Device Name: Syngo Carbon Space VA20A
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 16, 2022
Received: May 19, 2022

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*
K213665

Device Name
Syngo Carbon Space VA20A

Indications for Use *(Describe)*
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.

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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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:**
Siemens Healthcare GmbH
Henkestrasse 127
91052 Erlangen
Germany

2. **Establishment Registration Number:**
3004977335

3. **Contact Person:**
Mr. Vijay Ramadas
Regulatory Affairs Manager
Siemens Healthcare GmbH,
Siemensstr. 1
91301 Forchheim
Germany

E-mail: vijay.ramadas@siemens-healthineers.com
Telephone: +49 (172) 4324369
Fax: +49 (9191) 18-4404

4. **Device Name and Classification**

Device/Trade Name:	Syngo Carbon Space (VA20A)
Classifiation Panel:	Radiology
Classifiation Number:	21 CFR 892.2050
Classifiation Name:	Medical Image Management and Processing System
Device Class:	Class II
Product Code:	LLZ

5. **Legally Marketed Predicate Device:**

Device/Trade Name:	*syngo*.via (VB40A)
510(k) Clearance:	K191040
Clearance Date:	May 16, 2019
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ
Recall Information:	This predicate device has not been the subject of any design related recalls.

6. 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 is a medical device, provided in two variants/options.
- Diagnostic Workspace (Fat/Thick Client)
- Physician Access (Thin/Web Client)

In any scenario, both the options can be installed/run on the same machine and be used simultaneously.

Syngo Carbon Space Diagnostic Workspace 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.

Syngo Carbon Space Physician Access provides a zero-footprint web application for enterprise-wide viewing of DICOM, non-DICOM, multimedia data and clinical documents to facilitate image and result distribution in the healthcare institution.

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 this 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, Syngo Carbon

Space software version VA20A, as well as the predicate device, *syngo*.via, software version VB40A.

7. Intended Use:

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.

8. Indications for Use:

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.

9. 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	Impact to Safety & Effectiveness
Device name and version (K number)	Syngo Carbon Space VA20A	*syngo*.via VB40A (K191040)	New product	NA
Manufacturer	Siemens Healthcare GmbH	Siemens Healthcare GmbH	Same	NA
Indications for use	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.	*syngo*.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo* based software options. *syngo*.via supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.	Syngo Carbon Space is a device available in two options, - Diagnostic Workspace (Thick Client) - Physician Access (Web Client) with same intended use and Indications to use. Additionally, Syngo Carbon Space displays Non-DICOM Artifacts	Display of Non-DICOM artifacts in the subject device doesn't impact the safety and effectiveness of the device, as necessary measures have been taken

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Contraindications	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.	The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.	The subject device includes additional contraindication statements which acts as a caution to the user about the usage of the device while making a clinical decision from medical images or clinical documents.	The difference in 'contra-Indications' 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
Software architecture	Syngo Carbon Space is based on a client-server architecture	*syngo*.via is based on a client-server architecture	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
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) objects. Allows interfacing with HL7 (v2.5 / v2.3.1 / v2.3).	Syngo Carbon Space additionally allows communication with non-DICOM artefacts and FHIR interface	The difference in image communication 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
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 * available in in Diagnostic Workspace only	• 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	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Measurement, Evaluation/Interpretation Tools	• Distance (Distance line, Distance Polyline) • Angle • 2D ROI (Circle, Freehand, Polygonal, Auto Contour) * • 3D VOI (Sphere, Freehand) * • Pixel Lense • 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* • Time Curve, Time ROI* * available in in Diagnostic Workspace only	• Distance (Distance Line, Distance Polyline) • Angle • 2D ROI (Circle, Freehand, Polygonal) • 3D VOI (Sphere, Freehand) • Pixel Lens • Ranges (Parallel, Radial, Radial Sliced, Curved, Spine, Vascular) • Assisted Perpendicular Tool • Automatic Organ Segmentation • Interactive Tissue Segmentation • Time Curve, Time ROI • Define Vessel • SUV Measurement • Automatic Anatomy Labeling (rib, spine) • Basic Onco Tool (Assisted Perpendicular Tool) • Change Visualization • Next Study/ Previous Study	The evaluation/interpretation functionalities in the subject device are enhanced. <u>Lesion Quantification</u> Enables the user to perform diameter measurements and to create segmentation objects of suspect lesions in lung parenchyma. This is a non-Deep learning algorithm	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 • MG Image • MR Image • NM Image • PET Image • XA Image • US Image • Secondary capture objects	The subject device supports additional image object types for display: DICOM image object display: • ES Image • GM Image • OP/OPT Image • SM (WSI) 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, VP8, VP9,	This difference in supported DICOM modality and Non-DICOM object types 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
	VP8, VP9, WMV1, WMV2, WMV3 • Text Documents: CDA (XML), PDF		WMV1, WMV2, WMV3 • Text Documents: CDA (XML), PDF	

Operating system	<u>Diagnostic Workspace</u> Server • Microsoft Windows Server 2019 • Windows 10 IoT • Red Hat Enterprise Linux 8.4 Client • Microsoft Windows 10 (Pro, Pro-Education, Enterprise) <u>Physician Access</u> Server • Red Hat Enterprise Linux 8.4 Client – Workplace All operating systems that with support for the following HTML5- and JavaScript enabled browsers: • Google Chrome ≥ 83 (tested and recommended) • Microsoft Internet Explorer ≥ 11 (not recommended) • Microsoft Edge ≥ 83 (tested and recommended: Edge 89) • Mozilla Firefox ≥ 78 • Mozilla Firefox ESR ≥ 78 • Apple Safari ≥ 13 Client – Mobile device iPadOS ≥ 14, Safari web browser	<u>Windows client</u> • Microsoft Windows 7 SP1 • Microsoft Windows 8 (8.1 Pro, 8.1 Enterprise) • Microsoft Windows 10 (Home, Pro, Education, Enterprise) <u>Windows Server</u> • Microsoft Windows Server 2008 R2 • Microsoft Windows Server 2012 R2 • Microsoft Windows Server 2016	In the subject device client supports Microsoft Windows 10 Operating system and Server supports Microsoft Windows Server 2019, Windows 10 IoT, and Red Hat Enterprise Linux 8.4 compared to the predicate device.	This Operating System 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
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*.via 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 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).	*syngo.*via is used in Radiology, Nuclear Medicine, and Cardiology environments (e.g., darkened/ shaded rooms). 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 Space is based on a client-server architecture	*syngo*.via is based on a client-server architecture	Same	NA

Software self-test / checks	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.	Indicates the user in case that data coming from an interface cannot be assigned to a task flow to assign it manually. In case of a data mismatch due to incorrect or inconsistent use of DICOM rules the administrator can change the data transfer protocol and patient identification rules (DICOM Parser Tool). When the audit trail folder exceeds the configured level of storage, a warning message is sent to the administrator by e-mail, if configured. 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. Database recovery tool restores the data if the integrity checks between the Short term Storage and syngo.via database fails. A new instance of DICOM object is created in case of any non-reversible	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
		modification is performed on the DICOM Object (e.g. Lossy compression, reduction of color depth, resampling of image matrix, etc.)		
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 • Device guard (Whitelisting)	The security of the subject device was improved by enhancing the System Hardening at OS level as well as Network Level. OS level: The technologies (operating system, browser, web server etc.) used in IT systems attached to the network are hardened (configured securely) according to the IASE DISA standard. Network level: Provides protection to the system from malicious network traffic.	The improved security function doesn't impact the safety and effectiveness of the subject device as the necessary measures taken
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*.via.	Same	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
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
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 ** **available in Physician Access only	Simplified search functionality, clearer structure of search results, unlimited search results, periodic updates of search results, image preview, Correct & re-arrange and flexible floating patient browser window.	Syngo Carbon Space has an additional feature “Inbox”	The Inbox feature in the subject device doesn’t impact the safety and effectiveness of the device as necessary measures have been taken

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, 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	The Series Navigator lists all currently loaded data within a workflow. Series Navigator supports the Thumbnail view and switching between Preview, List and Thumbnail views for both series and instances level.	The functionality is enhanced in the subject device.	This series navigator 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
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 Navigator collects measurements, annotations, and graphical objects. Additionally, the user can create new findings, edit findings, trend findings over time, cluster findings based on body region.	The functionality is enhanced in the subject device. The Findings panel in the subject device additionally provides automatic findings creation option to create structured findings.	This difference in findings assistant 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
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)]	Findings and measurements are automatically sent to the syngo.*via* short Term Storage (STS) tracked and listed by the *syngo.via*. The radiologist can save or print a report, or send it to a connected information system, such as a HIS or RIS.	The reporting functionality in the subject device is modified and connected to third-party reporting solutions when compared to the predicate device.	This difference in reporting functionality 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
Image Archiving	<u>Diagnostic Workspace:</u> 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. <u>Physician Access:</u> Not applicable since Syngo Carbon Space Physician Access does not create data or images that is transferred/stored.	Data can be sent to an archive if *syngo*.via is connected to a PACS or corresponding DICOM node.	New option in the functionality of the subject device. The image archiving in the subject device takes place via syngo.share core option.	This difference of image archiving 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
Patient Jacket	Provides access to patient history – other studies of patient stored in syngo.share core or remote DICOM nodes. Also provides a study content preview.	The Add study dialog allows to query and retrieve studies from remote DICOM nodes for same patient	The Patient Jacket is enhanced with the feature, study content preview (thumbnail image for image series)	This difference of patient jacket 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
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 * available in in Diagnostic Workspace only	• 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	There are enhancements to the interaction tool algorithm in the subject device compared to the predicate device. <u>Magnifier</u> The Magnifier tool allows the user to magnify a section of the image in order to get a closer view of the section.	This difference in interaction tool 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
Annotation Tool	• Arrow* • Marker* • Text * available in in Diagnostic Workspace only	• Arrow • Marker • Text	Same	NA
Printing	Diagnostic workspace: Structured findings can be printed on a paper printer. Phyisican Access: Provides printing functionality on a paper printer.	Provides printing functionality at a DICOM printer or on paper printer. User may preview and re-arrange the images on the print sheet printing. The print sheet supports basic manipulations like zoom/pan and windowing.	Both the subject and predicate devices have the option for paper printing.	This difference in printing 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
Online help system	Yes, with search, indexing, filtering, library function and document collections.	Yes, with search, indexing, filtering, library function, document collections, and user-generated content.	Same	NA

10. 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

11. Bench Testing Evaluation Summary

The results of phantom and reader studies conducted on the Lesion Segmentation Algorithm 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 of the subject device and were found acceptable.

12. 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 Healthcare GmbH claims conformance to the following standards:

- NEMA PS 3.1 – 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set
- ISO/IEC 10918-1 First edition 1994-02-15 + Technical Corrigendum 1 (2005) (JPEG)
- 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
- IEEE Std 3333.2.1-2015

13. 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 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 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 Section B of this submission are our cybersecurity considerations as they relate to the device Syngo Carbon Space.

14. 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.

15. 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

16. 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 VA20A, does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device *syngo*.via VB40A.