



Siemens Healthcare GmbH
Vijay Ramadas
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Germany

December 1, 2023

Re: K232856

Trade/Device Name: Syngo Carbon Clinicals

Regulation Number: 21 CFR 892.2050

Regulation Name: Medical Image Management And Processing System

Regulatory Class: Class II

Product Code: QIH

Dated: November 14, 2023

Received: November 14, 2023

Dear Ramadas 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>).

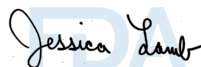
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless 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

Indications for Use

Submission Number (if known)

K232856

Device Name

Syngo Carbon Clinicals

Indications for Use (Describe)

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

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

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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September 15, 2023

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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2. Establishment Registration Number:

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4. Device Name and Classification

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

5. Predicate Device(s):

Main Predicate Device

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

Reference Device 1

Device/Trade Name: *syngo.via* RT Image Suite
510(k) Clearance: K220783
Classification Panel: Radiology Devices
Classification Number: 21 CFR 892.5050
Classification Name: Medical Charged-Particle Radiation Therapy System
Device Class: Class II
Product Code: MUJ

Reference Device 2

Device/Trade Name: *syngo.via*
510(k) Clearance: K191040
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

Reference Device 3

Device/Trade Name: *syngo.CT Lung CAD*
510(k) Clearance: K231157
Classification Panel: Radiology Devices
Classification Number: 21 CFR 892.2050
Classification Name: Medical Image Management and Processing System
Device Class: Class II
Product Code: OEB

6. Device Description:

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

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

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

7. Intended/Indications for use:

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

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

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

8. Technological Characteristics:

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

- **Cinematic insight** – An advanced visualization tool for cinematic rendering of anatomical structures using presets
- **Manual Calibration** – The Calibration tool is used manually calibrate non-calibrated images to enable measurement on such images
- Basic Onco Tools
 - **Assisted Perpendicular** – Tool to draw perpendicular distance lines to perform diameter measurements and thus to evaluate lesions
 - **Lesion Quantification** – Tool to perform diameter measurements (longest diameter, perpendicular diameter) and to create segmentation objects of suspect lesions in lung parenchyma with one click (semi automatically)
 - **Lung Nodule Marker** – Tool used to evaluate lung parenchyma for suspect lesions. This tool can also be used to evaluate lesions across different time points

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	Syngo Carbon Clinicals (VA30A)	Syngo Carbon Space (VA30A) K230561	New Product	NA
Manufacturer	Siemens Healthcare GmbH	Siemens Healthcare GmbH	Same	NA
Indications for use	<p>Syngo Carbon Clinicals is intended to provide advanced visualization tools to prepare and process the medical image for evaluation, manipulation and communication of clinical data that was acquired by the medical imaging modalities (for example, CT, MR, etc.)</p> <p>The software package is designed to support technicians and physicians in qualitative and quantitative measurements and in the analysis of clinical data that was acquired by medical imaging modalities.</p> <p>An interface shall enable the connection between the Syngo Carbon Clinicals software package and the interconnected software solution for viewing, manipulation, communication, and storage of medical images.</p>	<p>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.</p> <p>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.</p>	<p>The indications for use of Syngo Carbon Clinicals is a subset of the predicate. Subject device is used in qualitative and quantitative measurements and in the analysis of clinical data which is the same as the predicate device.</p> <p>Note: For our equivalency comparison, the Syngo Carbon Space "Diagnostic Workspace" shall be considered since the functionalities of Syngo Carbon Space "Physician Access" is not relevant to our subject device scope.</p> <p>The Predicate device additionally also is used for display and rendering of medical data.</p>	None

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Contraindications	<p>Syngo Carbon Clinicals is not indicated for mammography images for diagnosis in the U.S.</p> <p>Syngo Carbon Clinicals is not to be used as a sole basis for clinical decisions</p>	<p>Syngo Carbon Space "Diagnostic Workspace" is not intended for diagnosis of digital mammography images.</p> <p>Syngo Carbon Space "Diagnostic Workspace" is not intended to be used as a sole basis for clinical decisions.</p>	Same	None
Software architecture	Syngo Carbon Clinicals has architecture that is based on a layered pattern where the various clinical tools/functionality are decomposed into modules/common tools which provide their individual functionalities.	Syngo Carbon Space is based on a client-server architecture	A client server architecture is not used in the subject device due to the nature of the use of the subject device with the interfacing/hosting applications.	None
Image communication	Syngo Carbon Clinicals relies on the interfacing application for 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).	Syngo Carbon Clinicals does not have its own communication, it relies on the interfacing/hosting application for Image communication.	None

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Image display algorithms	<ul style="list-style-type: none"> • Rendering Tools: Cinematic Insight 	<ul style="list-style-type: none"> • MPR: MPR, MPR Thick, • MPR/MPR* • MIP: MIP, MIP Thin • MinIP View • VRT*: Plain VRT, Adapt VRT, • VRT Thin, Cinematic VRT (cVRT) • Fused View * • Invert Image <p>* available in in Diagnostic Workspace only</p>	<p>Syngo Carbon Clinicals provides the rendering tool: Cinematic Insight which is a combination of the Automatic Organ segmentation and the cVRT technique of image display which is available in the predicate device.</p> <p>This feature uses a deep learning algorithm for organ segmentation (algorithm that was cleared as part of the reference device syngo.via RT Image suite (K220783).</p> <p>No changes have been made to this algorithm compared to the reference device</p> <p>The segmented organ is then rendered using the cVRT technique available in the predicate device.</p>	<p>This feature does not impact the safety and effectiveness of the subject device as the necessary measures are taken</p>

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Measurement, Evaluation/Interpretation Tools	<ul style="list-style-type: none"> • Oncological evaluation: <ul style="list-style-type: none"> ○ Lesion Quantification ○ Assisted Perpendicular Tool ○ Lung Nodule Marker • Orthopaedic measurements: <ul style="list-style-type: none"> ○ Manual calibration 	<ul style="list-style-type: none"> • Lesion Quantification* • Assisted Perpendicular Tool* • Automatic Organ Segmentation* • Distance (Distance line, Distance Polyline) • Angle • 2D ROI (Circle, Freehand, Polygonal, Auto Contour) * • 3D VOI (Sphere, Freehand) * • Pixel Lens • Ranges (Parallel, Radial, Radial Sliced, Curved, Spine) * • Interactive Tissue Segmentation* • Time Curve, Time ROI* • SUV Measurement* • Automatic Anatomy Labeling (rib, spine) * • Next Study/ Previous Study* <p>* available in in Diagnostic Workspace only</p>	<p>Lung Nodule Marker tool is used to evaluate the lung for suspected lesions across time points.</p> <p>Manual calibration tool is a simple linear tool, where the user input of measurement is required for calibration of the image using a known size display image/an object of known size is available in the image</p>	<p>This feature does not impact the safety and effectiveness of the subject device as the necessary measures are taken</p>

<p>Supported objects for display</p>	<p>DICOM image object display</p> <ul style="list-style-type: none"> • CT Image • DX Image • CR Image 	<p>DICOM image object display:</p> <ul style="list-style-type: none"> • 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 <p>DICOM non-image object display:</p> <ul style="list-style-type: none"> • ECG • Encapsulated PDF • PR <p>Non-DICOM file display:</p> <ul style="list-style-type: none"> • Images: BMP, GIF, JPEG (JFIF), JPEG 2000, JPEG-LE, JPEG-LS, PCX, PNG, PNM, TIFF, WBMP • Video: FLV, H.264, H.265, 	<p>The supported objects for display in the subject device is a subset of the predicate device.</p>	<p>None</p>
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Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
		INDEO2, INDEO3, INDEO4, MPEG1, MPEG2, MPEG4, VP8, VP9, WMV1, WMV2, WMV3 Text Documents: CDA (XML), PDF		

<p>Operating system</p>	<p>None</p>	<p>Diagnostic Workspace</p> <p>Server</p> <ul style="list-style-type: none"> • Microsoft Windows Server 2019 • Windows 10 Enterprise • Red Hat Enterprise Linux 8.4 <p>Client</p> <ul style="list-style-type: none"> • Microsoft Windows 10 (Pro, Pro-Education, Enterprise) <p>Physician Access</p> <p>Server</p> <ul style="list-style-type: none"> • Red Hat Enterprise Linux 8.4 <p>Client</p> <p>All operating systems that with support for the following HTML5- and JavaScript enabled browsers:</p> <ul style="list-style-type: none"> • Google Chrome \geq 83 (tested and recommended) • Microsoft Internet Explorer \geq 11 (not recommended) • Microsoft Edge \geq 83 (tested and recommended: Edge 89) • Mozilla Firefox \geq 78 • Mozilla Firefox ESR \geq 78 • Apple Safari \geq 13 	<p>The interfacing/hosting application to Syngo Carbon Clinicals provides the operating system which the plug-in can use</p>	<p>None</p>
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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 Clinicals provides advanced visualization tools to prepare and process the medical images and it has no influence on the image acquisition devices	None Syngo Carbon Space is a pure viewing and/or post-processing software and it has no influence on the image acquisition devices	Same	None
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	None
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	None
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	None
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	None

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Intended use environment	Syngo Carbon Clinicals offers a wide range of tools from the major clinical fields, i.e. general radiology, oncology environments.	Syngo Carbon Space “Diagnostic Workspace” is used in Radiology, Nuclear Medicine and Cardiology environments (e.g., darkened/ shaded rooms).	Same	None
Intended user(s)	Trained healthcare professionals	Trained healthcare professionals	Same	None
Device Type	Software application	Software application	Same	None
Cyber Security	The cybersecurity aspects for Syngo Carbon Clinicals is handled by the interfacing/hosting system.	<p>User access control</p> <ul style="list-style-type: none"> • Audit Trail • Documentation of system security information, Network traffic & Firewall control • Support of virus / malware protection • System Hardening (OS level and Network level) 	Syngo Carbon Clinicals applications are running as a part of the interfacing device. The aspects for cybersecurity are assessed and provided to the interfacing application.	None
Hardware	Hardware is not understood as part of the medical device but needs to comply with the minimum requirements as specified by Syngo Carbon Clinicals	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	None

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Graphical user interface	Not offered by Syngo Carbon Clinicals	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.	The subject device utilizes the GUI provided by the interfacing application	None

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Patient Browser	Not offered by Syngo Carbon Clinicals	Search, browse & open data for display from syngo.share core & remote DICOM nodes <ul style="list-style-type: none"> • 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	NA	NA

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Series navigator / Document Preview	Not offered by Syngo Carbon Clinicals	<p>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).</p> <p>Study / Timepoints are marked with individual colors for better identification.</p> <p>The Series Navigator is called Document Preview for Physician Access.</p> <p>* available in in Diagnostic Workspace only</p>	NA	NA
Findings panel	Not offered by Syngo Carbon Clinicals	<p>Findings panel collects measurements, annotations, and graphical objects.</p> <p>Additionally, the user can create new findings, edit findings. It also allows creation of automatic findings.</p>	The subject device utilizes the findings panel provided by the interfacing application	None

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Reporting	Not offered by Syngo Carbon Clinicals	<p>No dedicated report creation functionality supported in Syngo Carbon Space.</p> <p>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])]</p>	The subject device utilizes the Reporting functionality provided by the interfacing application	None
Image Archiving	Not offered by Syngo Carbon Clinicals	<p>Diagnostic Workspace: Syngo Carbon Space Diagnostic Workspace does not store data or images.</p> <p>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.</p> <p>Physician Access: Not applicable since Syngo Carbon Space Physician Access does not create data or images that is transferred/stored.</p>	The subject device utilizes the archival functionality provided by the interfacing application	None

Specification	Subject Device	Predicate Device	Comparison	Impact to Safety & Effectiveness
Annotation Tool	Not offered by Syngo Carbon Clinicals	<ul style="list-style-type: none"> • Arrow* • Marker* • Text * available in in Diagnostic Workspace only	The subject device utilizes the annotation functionality provided by the interfacing application	None
Printing	Not offered by Syngo Carbon Clinicals	Diagnostic workspace: Structured findings can be printed on a paper printer. Physican Access: Provides printing functionality on a paper printer	The subject device utilizes the Printing functionality provided by the interfacing application	None
Online help system	Yes, with search, indexing, filtering, library function and document collections	Yes, with search, indexing, filtering, library function and document collections.	Same	Nonoe

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

Lesion Quantification: 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 and 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.

Organ Segmentation: The results of phantom and reader studies conducted on the Organ Segmentation Algorithm, in the reference 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 without any modifications.

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 reference device is still applicable for the subject device.

12. 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

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 Clinicals during product development.

The Risk Analysis was completed, and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

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

14. Summary:

Performance tests were conducted to test the functionality of the device Syngo Carbon Clinicals. 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 Clinicals, software version VA30A, 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.