December 21, 2023

Siemens Healthcare GmbH
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
SAINT PAUL, MN 55114

Re: K232744
Trade/Device Name: syngo Virtual Cockpit (VB10A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 18, 2023
Received: December 18, 2023

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.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
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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.

Submission Number *(if known)*

K232744

Device Name

syngo Virtual Cockpit (VB10A)

Indications for Use *(Describe)*

syngo Virtual Cockpit is a software application intended for remote operation, assistance, review, monitoring, and standardization of medical imaging devices. It is a vendor neutral solution allowing read-only or full access control to connected devices. syngo Virtual Cockpit is also intended for training of medical personnel working on the medical imaging devices.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

syngo Virtual Cockpit (Version VB10A)

K232744

In accordance with 21 CFR §807.92, the following summary of safety and effectiveness is provided.

I. SUBMITTER

21CFR § 807.92(a)(1)

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Henkestr. 127
91052 Erlangen
Germany

Contact: Dr. Jiayan Liu
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Email: jiayan.liu@siemens-healthineers.com

Date Prepared: July 4, 2023

II. DEVICE

21CFR § 807.92(a)(2)

Device Trade Name	*syngo* Virtual Cockpit (VB10A)
Classification Name	Medical image management and processing system
Common Name	System, Image Processing, Radiological
Classification Panel	Radiology
Regulation Number	§892.2050 Medical image management and processing system
Product Code	LLZ

III. LEGALLY MARKETED PREDICATE DEVICES

21CFR § 807.92(a)(3)

Predicate Device

Device Trade Name	Customer Remote Console
510(k) Number	K150193
Product Code	LLZ

This predicate has not been subject to a design-related recall.

Reference Device

Device Trade Name	*syngo* Expert-i
510(k) Number	K052423

Product Code LNH

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION SUMMARY

21CFR § 807.92(a)(4)

This premarket notification addresses the Siemens Healthineers *syngo* Virtual Cockpit (Version VB10A) Medical Image Management and Processing System (MIMPS).

syngo Virtual Cockpit (sVC) is a software solution for geographically distant technologist or radiologists to remotely assist with operating imaging equipment and radiotherapeutic devices.

sVC provides a private, secure communication platform for real-time image visualization and cross-organizational collaboration between healthcare professionals across multiple sites. sVC enables remote access to modality consoles and enhances communication capabilities between healthcare professionals across different locations. It is vendor-neutral and applicable to existing multimodalities in a healthcare network, a solution that allows healthcare professionals to share expertise and increase productivity, even when they are not physically present in the same location.

sVC is based on a client server architecture, with sVC server as the backbone and 3 different variants of client, based on the user roles, Modality client, Steering client & Physician client. Modality client as two flavors one windows based client and a web client which can be hosted in a web browser. Steering client establishes remote connection to Modality console / Modality acquisition workplace through KVM (Keyboard, Video and Mouse) switch or Siemens proprietary accessing tool, *syngo* Expert-i. Steering client can establish connections to more than one (up to 3) Modality console applications. Physician client is the third client for Physician that can be contacted either by Steering technologist or by Modality technologist for assistance regarding scanning in more complex cases, or the Physician can provide expert radiologist knowledge. The connection is possible in full control or read-only mode. The full-control accessibility to CT scanners is limited to the software associated with the modality workplace and is not applicable to the physical switches controlling the equipment operation. The connection to radiotherapeutic equipment is limited to be read-only.

In addition to enabling remote access and control of the modality scanners, sVC also supports common communication methods including live videos at the modality site, audio calls and text chats among users.

V. INTENDED USE/INDICATIONS FOR USE

21CFR § 807.92(a)(5)

Indications for Use Comparison

Predicate Device **Customer Remote Console** **K150193**	**Reference Device** ***syngo* Expert-I** **K052423**	**Subject Device** ***syngo* Virtual Cockpit VB10A**
The Customer Remote Console Software Option allows remote access for viewing/review of images as well as the ability to remotely provide real time guidance to the technologist operating GE Healthcare medical imaging devices. This access must be granted by the	The *syngo* Expert-i feature allows the local user of the MRI (e.g. tech) to get help and assistance from other personnel of the radiology department (e.g. other tech or physician) to perform scans faster and with better quality. For this purpose, a remote user within the local	*syngo* Virtual Cockpit is a software application intended for remote operation, assistance, review, monitoring and standardization of medical imaging devices. It is a vendor neutral solution allowing read-only or full access control to connected devices. *syngo* Virtual

technologist operating the system. The remote access is only available for systems supporting GE remote connectivity capability. Images reviewed remotely are not for diagnostic use.	network of the MRI (i.e. the network of the radiology) can log onto the MR main or satellite console.	Cockpit is also intended for training of medical personnel working on the medical imaging devices.

The intended use of subject device *syngo* Virtual Cockpit (version VB10A), predicate device Customer Remote Console and reference device *syngo* Expert-i is equivalent in that they all enable remote access to medical imaging devices and provide assistance to on-site technologists (Table 2). The subject, predicate and reference devices all allow remote users to help and assist modality technologist to display and review scanning protocols, observe and monitor the image acquisition and therefore help standardize scans in one institution. The intended use of the subject, predicate and reference devices to work with modality scanners is equivalent.

None of the subject, predicate and reference devices is indicated for any specific disease, condition, or patient population, and all are intended to support healthcare professionals in the healthcare institutions' environment. This similarity indicates that they share a broad scope of application and are not intended for a specific subset of patients or clinical scenarios. They can be considered substantially equivalent in their clinical versatility.

Indications for Use/Intended Use Comparison Summary and Conclusion

The Indications for Use were assessed in accordance with the following FDA Guidance Documents:

- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

The results of this evaluation determined that the Indications for Use for the subject, device and the predicate device are similar with expanded capability of intended use. As such, Siemens Healthineers is of the opinion that the Intended Use and Indications for Use are similar to the predicate device.

VI. COMPARISON OF FEATURES AND SPECIFICATIONS WITH THE PREDICATE DEVICE

21CFR § 807.92(a)(6)

Attribute	Predicate Device Customer Remote Console K150193	Reference Device *syngo* Expert-i K052423	Subject Device *syngo* Virtual Cockpit VB10A	Equivalency Analysis with predicate device
General Information				
Type of Software	Software in a Medical Device (SiMD)	Software in a Medical Device (SiMD)	Software as a Medical Device (SaMD)	equivalent
Device	System, Image Processing, Radiological	System, Nuclear Magnetic Resonance Imaging	System, Image Processing, Radiological	Identical
Regulation	§ 892.2050 Medical image management and processing system	§ 892.1000 Magnetic resonance diagnostic device	§ 892.2050 Medical image management and processing system	Identical
Product Code	LLZ	LNH	LLZ	Identical
Clinical Characteristics				

Attribute	Predicate Device Customer Remote Console K150193	Reference Device *syngo* Expert-i K052423	Subject Device *syngo* Virtual Cockpit VB10A	Equivalency Analysis with predicate device
Clinical condition the device is intended to diagnose, treat, or manage	Customer Remote Console is not indicated for any specific disease, or condition.	*syngo* Expert-i is not indicated for any specific disease, or condition.	*syngo* Virtual Cockpit is not indicated for any specific disease, or condition.	Identical
Intended patient population	Customer Remote Console does not have a limitation concerning the patient population (e.g., age, weight, health, condition).	*syngo* Expert-i does not have a limitation concerning the patient population (e.g., age, weight, health, condition).	*syngo* Virtual Cockpit does not have a limitation concerning the patient population (e.g., age, weight, health, condition).	Identical
Site of the body the device is intended to be used	No limitation concerning the site of the body the device is intended to be used.	No limitation concerning the site of the body the device is intended to be used.	No limitation concerning the site of the body the device is intended to be used.	Identical
Device Limitations	Not publicly available	*syngo* Expert-i is not to be used as the basis for medical diagnosis. *syngo* Expert-i is not to be used without clinical personnel at the medical imaging device who are trained according to local laws & regulations. *syngo* Expert-i is not suitable for use in facilities where a stable and reliable internet connection is not available.	*syngo* Virtual Cockpit is not to be used as the basis for medical diagnosis. *syngo* Virtual Cockpit is not to be used without clinical personnel at the medical imaging device who are trained according to local laws & regulations. *syngo* Virtual Cockpit is not suitable for use in facilities where a stable and reliable internet connection is not available. *syngo* Virtual Cockpit is not to be used to connect to medical devices which require control of two monitors when using KVM-Switches for connecting.	Equivalent to reference device. sVC provides a solution to connect to Siemens Healthineers MR scanners and show two screens in the similar way as the reference device.
Intended use environment	Healthcare facilities	Healthcare facilities	Healthcare facilities	Identical
Intended user(s)	Radiologist, Expert Technologist	persons with the certified specialist knowledge according to country-specific regulations, for example, physicians, trained radiologists or trained technologists, after an appropriate application training.	*syngo* Virtual Cockpit is intended for the following user profiles/user roles: • Steering Technologist • Modality Technologist • Physician • IT Administrator • Application Specialist • Service Technician • Implementation Engineer • Product Vendor/Business Unit	Identical. Described in different verbiage but identical in contents.

Attribute	Predicate Device Customer Remote Console K150193	Reference Device *syngo* Expert-i K052423	Subject Device *syngo* Virtual Cockpit VB10A	Equivalency Analysis with predicate device
Technical Characteristics				
Supported radiological devices	medical imaging devices	• MR	• medical imaging devices • Radiotherapeutic devices (linac), read only	equivalent
Supported vendors	GE	Siemens Healthineers	Vendor neutral	Different. sVC supports more vendors.
Remote Use	Yes	Yes	Yes	Identical
Connectivity requirements	Secured clinical network	Secured clinical network	Secured clinical network	Identical
Accessibility	Read only	Read only and full access	Read only and full access	Identical to reference device
Length of remote sessions	Not publicly available	Remote session remains active until manual disconnections. The connection automatically times out after a user defined idle time.	Remote session remains active until manual disconnections. The connection automatically times out after a user defined idle time.	Identical to reference device
User Interface Functions	PC-based	PC-based	PC-based	Identical
Operator Interface	Keyboard, Mouse, Video	Keyboard, Mouse, Video	Keyboard, Mouse, Video	Identical
Delay/latency	Not publicly available	Response time: <30 ms	Minimum requirements with one modality: Response time: ≤ 30 ms (Expert-i) / 60 ms (KVM)	Equivalent to reference device
Connection protocols	Not publicly available	VNC over TCP HTTPS over TCP	VNC over TCP HTTPS over TCP UDP (for chat, VolP)	Equivalent to reference device
Hardware	Software only solution. Requires standard computer and network hardware	Software only solution. Requires standard computer and network hardware	Software only solution. Requires standard computer and network hardware. KVM switch is required as a general network hardware for the connection to 3rd party scanners and radiotherapeutic equipment using KVM switch method.	Equivalent. The major deference is sVC requires a general IT network hardware KVM switch for its vendor neutral solution.
Operating system	Microsoft Windows	Microsoft Windows	Microsoft Windows	Identical
User Authorization and Authentication	Device requires user authentication and log on capabilities. User authorization is required for remote connection.	Device requires user authentication and log on capabilities. User authorization is required for remote connection.	Device requires user authentication and log on capabilities. User authorization is required for remote connection.	Identical

Attribute	Predicate Device Customer Remote Console K150193	Reference Device *syngo* Expert-i K052423	Subject Device *syngo* Virtual Cockpit VB10A	Equivalency Analysis with predicate device
Communication features	Screen sharing	Screen sharing	Screen sharing IP cameras for live video, Audio calls and chat	Equivalent. sVC has improved communication features.
Image acquisition	No.	Yes.	Yes. Limitation to trigger radiation exposure of CT scanners remotely.	Equivalent to reference device. The capability of MRI acquisition in sVC is the same as reference device.
Image processing, reporting and archiving	No image processing, reporting and archiving functionalities	No image processing, reporting and archiving functionalities	No image processing, reporting and archiving functionalities	Identical

The subject and predicate devices are both remote access technologies enabling remote collaborations and real-time communications between the onsite technologist and remote user. They share significant technological similarities in connectivity capabilities, network requirements, cybersecurity, software (operating systems) and hardware environment.

The major different technological characteristics resides in the sVC remote access by interfacing with a general IT infrastructure hardware, KVM switch. The verification and validation testing demonstrates that the sVC connection to modality scanners via KVM switch can perform as intended, meeting all of the design inputs. KVM switch connection related risks are mitigated to as far as possible. The technological difference with the subject device sVC does not constitute any new intended use and does not raise new questions of safety and effectiveness. Despite other differences in supported vendors, communication features, and other technical aspects, sVC has expanded device support, compatibility with multiple vendors, and enhanced communication features to address the evolving needs of healthcare settings, advancements in technology, or to provide additional functionality without compromising its intended use and purpose. The observed differences do not undermine the overall similarity and equivalence between the devices, as they can be explained by design improvements, expanded capabilities, or adaptations to meet evolving healthcare requirements.

Therefore, Siemens is of the opinion that syngo Virtual Cockpit VB10A does not raise new or different questions of safety or effectiveness and is substantially equivalent to the currently marketed predicate device Customer Remote Console.

VII. PERFORMANCE DATA

The following performance data were provided in support to demonstrate similarities to the predicate / previously cleared device.

Clinical Testing

21CFR § 807.92(b)(1)

No clinical studies were carried out for *syngo* Virtual Cockpit (Version VB10A). All performance testing was conducted in a non-clinical fashion as part of the verification and validation activities for the medical device.

Summary of Non-Clinical Testing

21CFR § 807.92(b)(2)

No performance standards for MIMPS have been issued under the authority of Section 514. Non-clinical testing was conducted for the device *syngo* Virtual Cockpit (Version VB10A) during product development. The features described in this Premarket Notification were supported with verification and validation testing.

Siemens Healthineers claims conformance to the following recognized consensus standards:

- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
- ISO 14971 Third Edition 2019-12
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION
- IEC TR 80001-2-2 Edition 1.0 2012-07
- IEC 82304-1 Edition 1.0 2016-10

Software Verification and Validation

In accordance with the FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, documentation is included within this submission for software of a Moderate Level of Concern. Software validation is performed using externally sourced representative modality scanners for the entire system in the Siemens Healthineers training center and at the clinical collaborating site. The system configuration, connectivity, compatibility and operation as well as risks associated with clinically relevant functions are assessed to validate the safety and effectiveness of the system in the simulated clinical environment and to validate the appropriateness and implementation of the intended use. Evidence provided within this submission demonstrates conformance with special controls for medical devices containing software.

Cybersecurity considerations related to *syngo* Virtual Cockpit are included within this submission. Siemens Healthineers conforms to cybersecurity requirements by implementing a means to prevent unauthorized access, modification, misuse, denial of use or unauthorized use of information stored, accessed or transferred from a medical device to an external recipient.

Risk Analysis, in compliance with ISO 14971 Third Edition, for *syngo* Virtual Cockpit (Version VB10A) 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 in support to determine similarities to the predicate /previously cleared device.

VIII. CONCLUSIONS

21CFR § 807.92(b)(3)

Performance tests were conducted to test the functionality of the device *syngo* Virtual Cockpit (Version VB10A). These tests have been performed to assess the functionality of the subject device. Results of all testing conducted were found acceptable in support to determine similarities to the predicate /previously cleared device.

Device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management was implemented throughout the development process to control potential hazards.

The device does not come in contact with the patient and is only used by trained professionals. The output of the device is evaluated by clinicians, providing for sufficient review to identify and intervene in the event of a malfunction.

Siemens Healthineers believes that *syngo* Virtual Cockpit (Version VB10A) is safe and effective as the identified predicate device and does not introduce new safety and effectiveness concerns.

Substantial Equivalence Conclusion

The comparison of intended use, technological characteristics, performance specifications, device hazards as well as verification and validation results demonstrate that *syngo* Virtual Cockpit is safe, effective and performs as well as the predicate device.

In summary, Siemens Healthineers is of the opinion that *syngo* Virtual Cockpit (Version VB10A) does not introduce any new significant potential safety risks and is similar to the predicate device.