February 4, 2025

roclub GmbH
% Mario Schrenk
Regulatory Affairs & QM Manager
Bismarckstraße 10-12
Berlin, Berlin 10625
GERMANY

Re: K243333
Trade/Device Name: rTOP
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 10, 2025
Received: January 10, 2025

Dear Mario Schrenk:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243333

Device Name

rTOP

Indications for Use *(Describe)*

roclub TeleOperationPlatform (rTOP) is a system (software application and hardware component) intended for remote operation, assistance, review, monitoring and standardization of medical imaging or diagnostic devices with video and optional USB (Universal Serial Bus) interface for HID (Human Interface Device). It is a vendor neutral solution allowing read-only or full access control to connected devices. rTOP is also intended for training of medical personnel working on the medical imaging devices. Other medical devices, especially therapeutic devices (e.g. radiotherapeutic devices, …) with video and optional USB (Universal Serial Bus) interface for HID (Human Interface Device) may be used read only.

rTOP is not indicated for any specific disease, or condition.

rTOP does not have a limitation concerning the patient population (e.g., age, weight, health, condition).

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.

510(k) Summary

Contact Information

Company Name	roclub GmbH
Address	Bismarckstraße 10-12, 10625 Berlin
Phone Number	00436703593947
Company Representative	Mario Schrenk, Regulatory Affairs & QM Manager
Email	mario.schrenk@roclub.com
Primary Correspondent	Mario Schrenk, Regulatory Affairs & QM Manager
Primary Correspondent Email	mario.schrenk@roclub.com
Date Summary Prepared	23. Oct. 2024

Device Information

Trade Name	rTOP
Common Name	teleoperation platform
Product Code	LLZ
Classification Name	Medical image management and processing system
Regulation Number	§892.2050
Class	Class II
Panel	Radiology

Predicate Device Information

Predicate Device Name	syngo Virtual Cockpit (VB10A)
Predicate Device K Number	K232744
Product Code	LLZ

Regulation Number	§892.2050
Class	Class II
Panel	Radiology

Device Description

roclub TeleOperationPlatform (rTOP) is a medical device (including hardware and software) for geographically distant technologist or radiologists to remotely assist with operating imaging equipment and radiotherapeutic devices.
rTOP provides a private, secure communication platform for real-time image visualization and cross-organizational collaboration between healthcare professionals across multiple sites. rTOP 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.
rTOP is
based on a client server architecture, with a cloud infrastructure as the backbone and 2 different variants of client, based on the user roles, local operator and remote operator. The remote operator app is a web client which runs in a web browser. The local operator establishes remote connection to the remote operator through the roclub connector (rC) including a video splitter and emulation of mouse and keyboard.
The remote operator can establish connections to more than one rC. Additional remote operators can connect for assistance or training purposes. The connection is possible in full control or read-only mode. The access to the system must be granted by the local user using the system. The access to the system can be revoked at any time by the local user, thus allowing the local user full control of the session at all times.
The full-control accessibility to higher risk modalities with physical switches (CT scanners) is limited to the software associated with the modality workplace and is not applicable to the physical switches controlling the equipment operation.
In addition to enabling remote access and control of the modality scanners, rTOP also supports common communication methods including live videos, audio calls and text chats among users.

rTOP allows full control of the connected devices, but for higher risk devices (e.g. LINACS, ...) rTOP only provides read-only access.

Indications for Use

roclub TeleOperationPlatform (rTOP) is a system (software application and hardware component) intended for remote operation, assistance, review, monitoring and standardization of medical imaging or diagnostic devices with video and optional USB (Universal Serial Bus) interface for HID (Human Interface Device). It is a vendor neutral solution allowing read-only or full access control to connected devices. rTOP is also intended for training of medical personnel working on the medical imaging devices. Other medical devices, especially therapeutic devices (e.g. radiotherapeutic devices, ...) with video and optional USB (Universal Serial Bus) interface for HID (Human Interface Device) may be used read only.

rTOP is not indicated for any specific disease, or condition.

rTOP does not have a limitation concerning the patient population (e.g., age, weight, health, condition).

Substantial Equivalence Discussion

In this chapter the differences between the predicate device and rTOP are discussed.

Predicate Device Indications for Use

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.

Subject Device Indications for Use

roclub TeleOperationPlatform (rTOP) is a system (software application and hardware component) intended for remote operation, assistance, review, monitoring and standardization of medical imaging or diagnostic devices with video and optional USB (Universal Serial Bus) interface for HID (Human

Interface Device). It is a vendor neutral solution allowing read-only or full access control to connected devices. rTOP is also intended for training of medical personnel working on the medical imaging devices. Other medical devices, especially therapeutic devices (e.g. radiotherapeutic devices, ...) with video and optional USB (Universal Serial Bus) interface for HID (Human Interface Device) may be used read only.

Indications for Use Equivalence Discussion

The Indications for Use for syngo Virtual Cockpit (predicate device) and TeleOperationPlatform (rTOP) are essentially equivalent. rTOP like syngo Virtual Cockpit does allow read-only or full access to the connected devices for a manifold of purposes. The two differences will be discussed in detail in chapter and leads to increased safety and effectiveness of rTOP.

Device Comparison Table

The following table describes the attributes of rTOP and the predicate device syngo Virtual Cockpit. Additionally in the comments column a comparison between rTOP and the predicate device is given. All attributes “Identical” will be discussed subsequently in chapter “Substantial Equivalence Discussion” in regards with new questions concerning safety and efficacy.

Attribute	rTOP	syngo Virtual Cockpit (VB10A) (K232744)	Comments
General Information			
Type of Software	SaMD + Hardware	SaMD	Hardware is part of rTOP
Device	System, Image Processing, Radiological	System, Image Processing, Radiological	Identical
Regulation	§ 892.2050 Medical image management and processing system	§ 892.2050 Medical image management and processing system	Identical
Product Code	LLZ	LLZ	Identical

Attribute	rTOP	syngo Virtual Cockpit (VB10A) (K232744)	Comments
Clinical Characteristics			
Clinical condition the device is intended to diagnose, treat, or manage	roclub TeleOperationPlatform 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	roclub TeleOperationPlatform 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.	Identical
Device Limitations	roclub TeleOperationPlatform is not to be used as the basis for medical diagnosis. roclub TeleOperationPlatform is not to be used without clinical personnel at the controlled medical device who are trained according to local laws & regulations. roclub TeleOperationPlatform is not suitable for use in facilities where a	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	Identical Identical Identical roclub Connector

Attribute	rTOP	syngo Virtual Cockpit (VB10A) (K232744)	Comments
	stable and reliable internet connection is not available.	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 KVMSwitches for connecting.	allows connection of 2 monitors, therefore the limitation is not given.
Intended use	roclub TOP is a system (software application and hardware component) intended for remote operation, assistance, review, monitoring and standardization of medical device with video and optional USB interface for HID. It is a vendor neutral solution allowing readonly or full access control to connected devices. roclub TOP is also intended for training of medical personnel working on the medical imaging devices.	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 readonly or full access control to connected devices. syngo Virtual Cockpit is also intended for training of medical personnel working on the medical imaging devices.	rTOP includes Hardware and has a generic definition of the connected/controlled devices.
Intended use environment	Healthcare facilities	Healthcare facilities	Identical
Intended user(s)	roclub TeleOperationPlatform	syngo Virtual Cockpit is intended	Identical

Attribute	rTOP	syngo Virtual Cockpit (VB10A) (K232744)	Comments
	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	for the following user profiles/user roles: • Steering Technologist • Modality Technologist • Physician • IT Administrator • Application Specialist • Service Technician • Implementation Engineer • Product Vendor/Business Unit	
Technical Characteristics			
Supported radiological devices	medical devices with video and optional USB interface for HID	- medical imaging devices - Radiotherapeutic devices (linac), read only	Generic definition of the connected devices.
Supported vendors	Vendor neutral	Vendor neutral	Identical
Remote Use	Yes	Yes	Identical
Connectivity requirements	Secured clinical network	Secured clinical network	Identical
Accessibility	Read only and full access	Read only and full access	Identical
Length of remote sessions	Remote session remains active until manual disconnections. The connection	Remote session remains active until manual disconnections. The connection	Identical

Attribute	rTOP	syngo Virtual Cockpit (VB10A) (K232744)	Comments
	automatically times out after a user defined idle time.	automatically times out after a user defined idle time.	
User Interface Functions	PC-based	PC-based	Identical
Operator Interface	Keyboard, Mouse, Video	Keyboard, Mouse, Video	Identical
Delay/latency	Minimum requirements with one modality: latencies up to 100 ms (warning above this level)	Minimum requirements with one modality: Response time: ≤ 30 ms (Expert-i) / 60 ms (KVM)	Equivalent
Connection protocols	HTTPS over TCP UDP (for WebRTC)	VNC over TCP HTTPS over TCP UDP (for chat, VoIP)	Identical (VNC functionality of predicate included in WebRTC of rTOP)
Hardware	Hardware (KVM, computer hardware) is included. Requires only network interfaces for access to the roclub cloud.	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
Operating system for App	Independent of OS (browser based)	Microsoft Windows	Equivalent
User Authorization	Device requires user authentication and log	Device requires user authentication and	Identical

Attribute	rTOP	syngo Virtual Cockpit (VB10A) (K232744)	Comments
and Authentication	on capabilities. User authorization is required for remote connection.	log on capabilities. User authorization is required for remote connection.	
Communication features	Screen sharing USB cameras for live video, audio calls and chat.	Screen sharing IP cameras for live video, Audio calls and chat.	Identical
Image acquisition	Yes. Depending on controlled medical device.	Yes. Limitation to trigger radiation exposure of CT scanners remotely.	Identical
Image processing, reporting and archiving	No image processing, reporting and archiving functionalities.	No image processing, reporting and archiving functionalities.	Identical

Substantial Equivalence Discussion

In this chapter the differences between the predicate device and rTOP are discussed in detail.

“Intended Use” and “Supported radiological devices”

There is two differences in the intended use:

- predicate: “software application” - rTOP:”: This is discussed extensively in the chapter “Type of software” and “Hardware”
- predicate: “of medical imaging devices” - rTOP: “medical imaging or diagnostic devices with video and optional USB (Universal Serial Bus) interface for HID (Human Interface Device)”:

The predicate device restricts its use to medical imaging devices in the indications for use, but lists “Radiotherapeutic devices (linac), read only” under supported radiological devices (see Device Comparison Table). rTOP allows control over medical imaging or diagnostic devices with video and optional USB

interface. This allows a slightly wider range of application. For higher risk devices this means “read only” as particular standards of the 60601 series do not allow remote control of devices like Linacs (see IEC 60601-2-64 Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment). Essentially this leads to the same use of both the predicate device and rTOP, which raises no new questions regarding safety and effectiveness.

“Type of software” and “Hardware”

rTOP is a vendor independent solution and as the predicate device needs hardware to be connected to medical devices. The predicate device needs a KVM switch as a general network hardware for the connection to 3rd party scanners and radiotherapeutic equipment using KVM switch method. This functionality is included in rTOP. The roclub Connector (rC) allows the functionality of the KVM.

The hardware is fully tested according to 60601-1 for electrical and mechanical safety. As discussed in the highest risks of rTOP are connected to electromagnetic compatibility. This is mitigated by testing according to 60601-1-2.

For normal KVM switches as needed by the predicate device this testing is not exectuted, therefore rTOP increases the safety of the user and the healthcare facility environment in general.

Additionally, because rTOP integrates the hardware, all verification and validation tests are executed including the necessary hardware. This leads to a higher expected effectiveness and less downtime of the full system.

The executed bench testing allows rTOP to increase the safety and effectiveness compared to the predicate device.

“Device limitations”

rTOP does not have the limitation to only control one monitor. This is a further benefit of the tailor made hardware of rTOP. This does not raise new questions regarding safety and effectiveness. The effectiveness of rTOP is increased, because the included hardware allows controll of devices, which use two monitors.

“Delay/latency”

The delay/latency of rTOP is comparable to the predicate device. Bench testing and usability testing show, that reactivity of rTOP is adequate. The comparable delay/latency of rTOP does not lead to new questions regarding safety of effectivenessy.

“Operating system for App”

rTOP does use its own OS on the rC and on the side of the remote user is not dependent on an operating system as it is used browser based. This does not raise any new questions regarding safety and leads to better effectiveness, because of fewer limitations and compatibility issues to access rTOP.

Conclusion

rTOP is substantially equivalent to the identified predicate device syngo Virtual Cockpit (VB10A) (K232744). Specifically, rTOP has similar intended use and technological characteristics compared to the previously cleared predicate device.

The differences, which were found comparing rTOP to the predicate device, have been discussed extensively. These differences in technological characteristics do not raise any new questions of safety and effectiveness and have been properly verified and validated through testing.

Therefore, rTOP is substantially equivalent to the predicate device.

Performance Data

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as
recommended by
2023 FDA Guidance “Content of Premarket Submissions for Device Software Functions”.

The software verification and validation testing verified that the design requirements were successfully met. The Intended use and user needs were successfully validated.

As the intended use, functionality and performance of the subject device and the predicate device are equivalent, the result of the performance testing is

evidence that the rTOP performs in an equivalent manner to the syngo Virtual Cockpit (VB10A).

Clinical Performance Testing

No clinical performance data was necessary to claim substantial equivalence.

Conclusion

The rTOP shares similar technological characteristics, intended use, and functionality with the predicate device. There are no differences between the devices that raise new questions of safety and effectiveness.

Furthermore, non-clinical performance test data and software verification and validation demonstrate that rTOP performs comparably to the predicate device in terms of safety and effectiveness.

Based on the device comparisons and the acceptable testing results, it is determined that rTOP is substantially equivalent to the predicate device.