October 24, 2024

Philips Medical Systems Nederland B.V.
% Rob Vingerhoed
Regulatory Affairs Manager
Veenpluis 6
5684 Pc
BEST,
NETHERLANDS

Re: K242512
Trade/Device Name: ROCC Console
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 23, 2024
Received: August 23, 2024

Dear Rob Vingerhoed:

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
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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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)*

K242512

Device Name

ROCC Console

Indications for Use *(Describe)*

ROCC Console is intended for remote scanning, support, review, monitoring and standardization of imaging protocols of medical imaging devices. It is a multi-vendor solution allowing view-only or full access control to connected devices. ROCC Console is also intended for training of medical personnel working on connected 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

Prepared on: 2024-10-23

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ROCC Console
Common Name	Medical image management and processing system
Classification Name	Medical image management and processing system
Regulation Number	892.2050
Product Code(s)	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232744	syngo Virtual Cockpit (VB10A)	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

This premarket notification addresses the Philips ROCC Console, a Medical Image Management and Processing System (MIMPS).

ROCC Console is a software device, which is part of the ROCC (Radiology Operations Command Center) system, a cloud-based solution which can connect expert radiology users located at a remote command center with onsite technologists operating an MR/CT scanner on-demand, while enabling real-time operational support/guidance for the technologists at the scanner console. This ROCC system allows healthcare professionals to share expertise, even when they are not physically present in the same location. Expert users are working from remote office locations within a healthcare facility or from a home office.
ROCC Console is a multiple function device product. The medical device functions include the ability to control ("edit") the console of a connected MR/CT scanner from a remote location, and a Protocol Management mode, which can be used to manage updates / harmonize scan protocols across connected MR/CT scanners.

ROCC Console is vendor neutral. It is intended to be used in healthcare environments including imaging modalities (MR or CT) with digital output (DP, DVI, and HDMI) which are either fixed to one location or are in mobile (truck) environments where medical imaging services are provided.

ROCC Console supports three connection methods to exchange the KVM (Keyboard, Video and Mouse) information between the expert user and the technologist. The proprietary software KVM connection includes two applications: a "Console Transmitter App" for use by the technologist on the scanner side, and a "Console Receiver App" for use by the remotely located expert user. The Console Transmitter App is a native Windows application installed on a desktop system, which sends the console video stream over the internet to the Console Receiver App. The Console Receiver App is a web-application that can run on a web browser, and receives and displays the video stream to the remotely located expert user. When the expert user edits the scanner console through mouse and keyboard entries, it sends these keyboard and mouse entries back to the Console Transmitter App, which subsequently sends these to the scanner console. Additionally, ROCC Console supports off-the-shelf HW/SW KVM switch or VNC. ROCC Console can be used with 3 MR/CT console connections concurrently.

When a patient is to be scanned, the on-site technologist must remain present at all times and retains full control over the MR/CT scanner console and can terminate the editing authorization at any time. For CT connections, full access is limited to what is available in the software associated with the modality workspace and is not applicable to physical switches controlling the radiation exposure.

The Protocol Management mode allows access to the MR/CT scanner console without a technologist on site. It is only intended for protocol management and harmonization and not for any remote imaging support.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

ROCC Console is intended for remote scanning, support, review, monitoring and standardization of imaging protocols of medical imaging devices. It is a multi-vendor solution allowing view-only or full access control to connected devices. ROCC Console is also intended for training of medical personnel working on connected medical imaging devices.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use / indications for use statements are near identical, except for a few minor differences in applied terminology (e.g., view-only vs read-only). As these differences have essentially the same meaning, these statements are substantially equivalent.

The description of the intended clinical users also differs in applied terminology. The description for the predicate device only refers to the user profiles as used in the accompanying Instructions for Use, whereas the description for the ROCC Console also describes the professional qualifications of the intended users. As both devices are only intended to be used by healthcare professionals with similar qualifications, and not by patients or lay persons, these statements are substantially equivalent.

The description of the intended use environment for ROCC Console is more specific, but substantially equivalent with the one for the predicate device. Both devices support flexibility in the location of use.

Therefore, it can be concluded that the intended use / indications for use for both the predicate device and the proposed ROCC Console are the same.

Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristics are identical for the following aspects
- Design (Software only)
- Multi-vendor compatibility
- Remote use
- Remote accessibility (expert user can remotely access the supported scanner and/or only view/read the scanner console
- Length of the remote sessions
- Connectivity requirements
- User interface functions
- Operator interface
- Operating system
- User authorization and authentication
- Image acquisition
- Image processing, reporting and archiving.

The following technological characteristics are considered substantially equivalent:
- Multi-modality / Hardware: ROCC Console supports MR and CT modality which is a subset of what the predicate device supports. Because it is a subset, it is regarded substantially equivalent.
- Delay / latency: the specified maximum latency of ROCC console is slightly higher than the predicate device. The specified maximum

latency of ROCC Console allows the performance and safety requirements of ROCC Console to be met. The difference with it's predicate is not significant.
• Connection protocols: both devices use VNC over TCP. ROCC Console also uses HW KVM over TCP for one of it's connection methods. This means the TCP protocol is used by both devices. Both devices use HTTPS connection protocols even though the data being exchanged is different, the use of the protocol is identical. The predicate device uses different terminology for the same connection protocol (UDP versus WebRTC-UDP for ROCC Console). Therefore this is substantially equivalent.
• Lastly: the ROCC system communication features offered are substantially equivalent.

Substantial equivalence was demonstrated with non-clinical performance testing. Verification and Validation (V&V) activities were performed on the proposed ROCC Console and demonstrated that the predetermined acceptance criteria were successfully met and no different questions in terms of safety and effectiveness were raised. The non-clinical performance tests provided in this 510(k) submission demonstrate that the proposed ROCC Console is as safe and effective as the predicate device, the syngo Virtual Cockpit (VB10A) (K232744).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Please see software verification and validation documents to support the performance of ROCC Console.

Not applicable.

All pre-specified performance metrics have been met as demonstrated within the software verification and validation documentation. The ROCC Console performs as intended.