June 17, 2025

Shanghai United Imaging Healthcare Co., Ltd.
% Xin Gao
RA Manager
No. 2258 Chengbei Rd. Jiading District
SHANGHAI, 201807
CHINA

Re: K243666
Trade/Device Name: uOmniscan
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 23, 2025
Received: May 23, 2025

Dear Xin Gao:

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 Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

Submission Number *(if known)*

K243666

Device Name

uOmniscan

Indications for Use *(Describe)*

uOmniscan is a software application for providing real-time communication between remote and local users, providing remote read-only or fully controlled access to connected medical imaging devices, including the ability to remotely initiate MR scans. It is also used for training medical personnel in the use of medical imaging devices. It is a vendor-neutral solution. Access must be authorized by the onsite user operating the system. Images reviewed remotely are not for diagnostic use.

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 **K243666**

1. **Date of Preparation:**
June 17, 2025

2. **Sponsor Identification**

Shanghai United Imaging Healthcare Co.,Ltd.
No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Establishment Registration Number: 3011015597

Contact Person: Xin GAO
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3. **Identification of Proposed Device**

Trade Name: uOmniscan
Common Name: Medical image management and processing system
Model(s): uOmniscan
510(k) Number: K243666

Regulatory Information
Classification Name: Medical image management and processing system
Classification: II
Product Code: LLZ
Regulation Number: 21 CFR 892.2050
Review Panel: Radiology

4. **Identification of Predicate Device(s)**

Predicate Device
510(k) Number: K232744
Device Name: syngo Virtual Cockpit (VB10A)

Reference Device#
510(k) Number: K232346

Device Name: Digital Expert Access with Remote Scanning

5. Device Description

uOmniscan is a medical software designed to address the skill differences among technicians and their need for immediate support, allowing them to interact directly with remote experts connected to the hospital network. By collaboration between on-site technicians and remote experts, it enables technicians or radiologists located in different geographic areas to remotely assist in operating medical imaging devices. uOmniscan provides healthcare professionals with a private, secure communication platform for real-time image viewing and collaboration across multiple sites and organizations.
uOmniscan establishes remote connections with Modality through application, KVM (Keyboard, Video, Mouse) switch, or UIH's proprietary access tool uRemote Assistant. The connection can be made in full control or read-only mode, assisting on-site technicians in seeking guidance and real-time support on scan-related issues, including but not limited to training, protocol evaluation, and scan parameter management, with the capability to remotely initiate scans for MR imaging equipment. In addition to supporting remote access and control of modality scanners, uOmniscan also supports common communication methods including real-time video, as well as audio calls and text chats between users.
Images viewed remotely are not for diagnostic purposes.
It is a vendor-neutral solution compatible with existing multimodality equipment in healthcare networks, allowing healthcare professionals to share expertise and increase work efficiency, while enhancing the communication capabilities among healthcare professionals at different locations.

6. Indications for use

uOmniscan is a software application for providing real-time communication between remote and local users, providing remote read-only or fully controlled access to connected medical imaging devices, including the ability to remotely initiate MR scans. It is also used for training medical personnel in the use of medical imaging devices. It is a vendor-neutral solution. Access must be authorized by the onsite user operating the system. Images reviewed remotely are not for diagnostic use.

7. Summary of Technological Characteristics

The technology characteristics of the proposed device reflected in this 510(k) submission are substantially equivalent to those of the predicate device and reference devices.

The following tables present a comparative analysis of the main features, principles of operation, fundamental scientific technology and intended use of the proposed device in relation to both predicate device and reference devices.

Table 1 General information comparison

Item	**Proposed Device** uOmniscan (K243666)	**Predicate Device** syngo Virtual Cockpit (VB10A) (K232744)	**Remark**
Device Classification Name	Medical Image Management and Processing System	Medical Image Management and Processing System	Same
Product Code	LLZ	LLZ	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Device Class	II	II	Same
Classification Panel	Radiology	Radiology	Same
Intended Use	uOmniscan is a software application for providing real-time communication between remote and local users, providing remote read-only or fully controlled access to connected medical imaging devices, including the ability to remotely initiate MR scans. It is also used for training medical personnel in the use of medical imaging devices. It is a vendor-neutral solution. Access must be authorized by the onsite user operating the system. Images reviewed remotely are not for diagnostic 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.	The description of the predicate device is slightly different from the proposed device. The difference will not impact the safety and effectiveness of the device.

Table 2 Comparison between Proposed Device and Predicate and Reference Device

Item	**Proposed Device** uOmniscan (K243666)	**Predicate Device** syngo Virtual Cockpit (VB10A) (K232744)	**Reference Device** Digital Expert Access with Remote Scanning (K232346)	**Remark**
User Interface Functions	PC-based	PC-based	/	Same
Operator Interface	Keyboard, Mouse, Video	Keyboard, Mouse, Video	/	Same
Communication features	Screen sharing, video, Audio calls and chat	/	Screen sharing, video, Audio calls and chat	Same
Accessibility	Read only and full access	Read only and full access	Read only and full access	Same
Imaging System Modality for Remote Scanning	MR	MR	MR	Same
Intended Users	Radiologist, Expert,Technologist	Radiologist, Expert,Technologist	Radiologist, Expert,Technologist	Same
Supported radiological devices	medical imaging devices	/	medical imaging devices	Same
Scan Initiation	Remote user can initiate scan on MR scanners remotely	Remote user can initiate scan on MR scanners remotely	Remote user can initiate scan on MR scanners remotely	Same
Supported vendors	Vendor neutral	Vendor neutral	/	Same
Hardware	Software only solution. Requires standard computer and network hardware. KVM switch is required as a	Software only solution. Requires standard computer and network hardware. KVM switch is required as a	/	Same

	general network hardware for the connection to 3rd party scanners equipment using KVM switch method.	general network hardware for the connection to 3rd party scanners equipment using KVM switch method.		
Patient/Scanner Support during Acquisition	Onsite technologist oversees patient support during scanning acquisition	Onsite technologist oversees patient support during scanning acquisition	Onsite technologist oversees patient support during scanning acquisition	Same

Note 1:

uRemote Assistant(cleared in K240540), uRemote Assistant is a tool of the scanner system, used for remotely controlling the Scanner over the network, uRemote Assistant is a tool of the scanner system, used for remote connection to the scanner device via network. Does not affect product safety and effectiveness.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility
Not Applicable to the proposed device, because the device is stand-alone software.

Electrical Safety and Electromagnetic Compatibility (EMC)
Not Applicable to the proposed device, because the device is stand-alone software.

Software
Software verification and validation testing was provided to demonstrate safety and efficacy of the proposed device.

Animal Study
No animal study was required.

Clinical Studies
No clinical study was required.

Performance Verification
Evaluation testing was conducted to verify the functions defined in the intended use of the proposed device, including:

- Establishing a real-time communication between remote and local users
- Establishing a session with fully control to connect medical image device with uRemote Assistant
- Establishing a session with fully control to connect medical image device with KVM Switch
- Network Status Identification
- Evaluating Performance for different network conditions/speeds
- Indicating network state to users

Usability Study
Expert review for formative evaluation and usability testing for summative evaluation were conducted for usability study, which involves participation of experts and user representatives. Testing results are as follows:

- Design of user interface and manual effectively decrease the probability of use errors.

- All risk control measures are implementable and understood across user expertise levels.
- The product has no unacceptable residual use-related risks.

Other Standards and Guidance

- ISO 14971 Medical devices - Application of risk management to medical devices (Third Edition 2019-12).
- IEC 62304 Medical device software - Software life cycle processes (Edition 1.1, 2015).
- IEC 82304-1 Edition 1.0 2016-10 Health software - Part 1: General requirements for product safety

9. Substantially Equivalent (SE) Conclusion

The proposed device is equivalent to the predicate device and reference device in regard to safety and efficacy. This conclusion is based upon a comparison of intended use, technological characteristics, performance specification, device hazards as well as verification and validation results.

In summary, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device and reference device.