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

Re: K230039
Trade/Device Name: Medical Image Post-processing Software, Model: uOmnispace
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: June 20, 2023
Received: June 20, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, Ph.D.
Assistant Director
Imaging Software 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230039

Device Name

uOmnispace

Indications for Use *(Describe)*

uOmnispace is a software solution intended to be used for viewing, manipulation, communication and storage of medical images. It allows processing and filming of multimodality DICOM images.

It can be used as a stand-alone device or together with a variety of cleared and unmodified software options, and also support to plug in multi-vendor applications which meet interface requirements.

uOmnispace is intended to be used by trained professionals, including but not limited to physicians and medical technicians.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

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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510 (k) SUMMARY

1. Date of Preparation:

June 20, 2023

2. Sponsor Identification

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No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Establishment Registration Number: 3011015597

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Position: Regulatory Affairs Manager
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3. Identification of Proposed Device

Trade Name: Medical Image Post-processing Software
Common Name: Medical image management and processing system
Model(s): uOmnispace

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

4. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K191040
Device Name: syngo.via
Classification: II
Product Code: LLZ

Reference Device
510(k) Number: K183170
Device Name: uWS-CT
Classification: II
Product Code: LLZ

5. Device Description

uOmnispace is a software only medical device, the hardware itself is not seen as part of the medical device and therefore not in the scope of this product.
uOmnispace provides 2D and 3D viewing, annotation and measurement tools, manually and automatically segmentation tools (Rib extraction algorithm is based on Machine Learning) and film and report features to cover the radiological tasks reading images and reporting. uOmnispace supports DICOM formatted images and objects, CT, MRI, PET and DR multimodality are supported.
uOmnispace is a software medical device that allows multiple users to remotely access clinical applications from compatible computers on a network. The system allows processing and filming of multimodality DICOM images. This software is for use with off the-shelf PC computer technology that meets defined minimum specifications.

uOmnispace communicates with imaging systems of different modalities and medical information systems of the hospital using the DICOM3.0 standard.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

6. Indications for use

uOmnispace is a software solution intended to be used for viewing, manipulation, communication and storage of medical images.

It can be used as a stand-alone device or together with a variety of cleared and unmodified software options, and also support to plug in multi-vendor applications which meet interface requirements.

uOmnispace is intended to be used by trained professionals, including but not limited to physicians and medical technicians.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

7. Summary of Technological Characteristics

The technology characteristics of uOmnispace, reflected in this 510(k) submission is substantially equivalent to those of the predicate device.

The following tables compare the technology and intended use of uOmnispace when compared to the predicate devices.

Table 1 Substantial equivalent discussion for basic functions

Item	**Proposed Device** uOmnispace	**Predicate Device** syngo.via (K191040)	**Reference Device** uWS-CT (K183170)	**Comparison**
Device Classification Name	Medical image management and processing system	Medical image management and processing system	/	Same
Product Code	LLZ, QIH	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	uOmnispace is a software solution intended to be used for viewing, manipulation, communication and storage of medical images. It allows processing and filming of multimodality DICOM images. It can be used as a stand-alone device or together with a variety of cleared and unmodified software options，and also support	syngo.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified syngo based software options.	/	Substantial Equivalence This difference between the predicate device and the proposed device is about description, it doesn't impact the safety and effectiveness of the subject device.

	to plug in multi-vendor applications which meet interface requirements. uOmnispace is intended to be used by trained professionals, including but not limited to physicians and medical technicians. The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.	syngo.via supports interpretation and evaluation of examinations within healthcare institutions, For example, in Radiology, Nuclear Medicine and Cardiology environments. The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.		
Client-Server Architecture and Multi-User Access	Yes Based on client-server architecture and supports multi-user access.	Yes Based on client-server architecture and supports multi-user access.	/	Same
Image communication and storage	Yes Communicate and store medical images based on standard communication protocol DICOM.	Yes Communicate and store medical images based on standard communication protocol DICOM.	/	Same
Hardware /OS	Yes Client: Microsoft Windows 7 or Microsoft	Yes Client: Microsoft Windows 7 SP1 or Microsoft	/	Functional Substantially Equivalent The client and server operating systems of the proposed device are Microsoft Windows and Linux respectively, while those of the

	Windows 10 or compatible versions Server: Linux Core CentOS7.7 or compatible versions	Windows 8.1 or Microsoft Windows 10 Server: Microsoft Windows Server 2008 R2 or Microsoft Windows Server 2012 R2. or Microsoft Server 2016		predicate device are Microsoft Windows and Microsoft Windows Server respectively. This difference doesn't impact the safety and effectiveness of the subject device.
Workflow control	Yes Pre-processing: Auto process images before loading into post-processing applications. The client workflow supports both single monitor and dual monitors.	Yes Workflows support the user in preparing images for examination. Supports various monitor setups workflow.	/	Functional Substantially Equivalent Pre-processing is equivalent to part of the "preparing images for examination", the predicate device also assigns the examination to an application. This difference doesn't impact the safety and effectiveness of the subject device.
Patient Administration	Yes Patient administration displays the patient data and offers the function of searching, sorting, and editing of patient data and image preview.	Yes With simplified search functionality, clearer structure of search results, unlimited search results, periodic updates of search results, image preview and flexible floating patient browser window.	/	Functional Substantially Equivalent The proposed device does not support flexible floating patient browser window. This difference doesn't impact the safety and effectiveness of the subject device.
Review 2D	Yes	/	Yes	Same

	2D image viewing, Textual and graphical annotations，distance, angle, ROI, image addition and subtraction, image filter are supported.		2D image viewing, Textual and graphical annotations，distance, angle, ROI, image addition and subtraction, image filter are supported.	
Review 3D	Yes 3D image viewing, Save 3D images in batches. Segmentation functions such as CT bone removal tools, CT/MR tissue growing tools, VOI, cut.	/	Yes 3D image viewing. Save 3D images in batches. Segmentation functions such as CT bone removal tools, CT tissue growing tools, VOI, cut.	Same
Review 3D algorithm	Yes Volume rendering (VR) with Hyper Realistic Rendering (HRR), Multi-Planar Reconstruction (MPR), Maximum Intensity Projection (MIP), Minimum Intensity Projection (MinIP), Curved Planar Reformation (CPR), Surface-shaded Display (SSD). Automatic body bone removal algorithm		Yes Volume rendering (VR), Multi-Planar Reconstruction (MPR), Maximum Intensity Projection (MIP), Minimum Intensity Projection (MinIP), Curved Planar Reformation (CPR), Surface-shaded Display (SSD). Automatic body bone removal algorithm	Functional Substantially Equivalent HRR is an extension to the standard VR rendering algorithm to visualize the photorealistic images. This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the proposed device.

	Automatic head bone removal algorithm		Automatic head bone removal algorithm	
Rib segmentation	Yes Machine learning based algorithm	/	Yes Threshold based interactive algorithm	Functional Substantially Equivalent Both are used for rib segmentation, the reference device requires interaction, while the proposed device does not. This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the proposed device
Inner view	Yes 3D virtual endoscopy view and extract the centerline of vessel, airway and colon. Imaging algorithms: CT colon Inner View algorithm CT vessel Inner View algorithm CT lung trachea Inner View algorithm MR vessel Inner View algorithm	/	Yes 3D virtual endoscopy view and extract the centerline of vessel, airway and colon. Imaging algorithms: CT colon Inner View algorithm, CT vessel Inner View algorithm CT lung trachea Inner View algorithm	Functional Substantially Equivalent The MR vessel Inner View algorithm is same with CT vessel Inner View algorithm, the difference of input modality does not affects the output. This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the proposed device.
Filming	Yes	/	Yes	Same

	Support to print image and selection of printer.		Support to print image and selection of printer.	
Report	Yes Support to create reports, text editing and image inserting，customize report template, exporting and printing of report.	/	Yes Support to create reports, text editing and image inserting，customize report template, exporting and printing of report.	Same
Archiving	Yes Import of DICOM images from configured network nodes (modalities, medical imaging process software, PACS, etc) or local and network drives or DVD/CD. Export (archive) DICOM images to network nodes, or local and network drives or DVD/CD.	Yes Import of DICOM data from network nodes or external media, and of DICOM-compliant or non DICOM compliant data from external media and Windows file system. Export to CD/DVD, Windows file system, or other DICOM nodes.	/	Functional Substantially Equivalent The proposed product does not support to import non DICOM compliant data from external media and Windows file system. This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the proposed device

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 Verification and Validation

Software verification and validation testing was provided to demonstrate safety and efficacy of the proposed device. This includes a hazard analysis, and the potential hazards have been classified as a moderate level of concern (LOC). Those documentations include:

- Software Description
- Device Hazard Analysis
- Software Requirements Specification
- Software Architecture Design Chart
- Software Development Environment Description
- Software Verification and Validation
- Cybersecurity Documents

Animal Study

No animal study was required.

Clinical Studies

No clinical study was required.

Performance Verification

To validate the uOmnispace software from a clinical perspective, the ML-based rib segmentation algorithm contained in the product underwent a scientific evaluation. The results of clinical data-based software validation for the subject device demonstrated equivalent performance in comparison to the reference device.

The performance testing for ML-based rib segmentation algorithm was performed on 60 subjects (data shown in Table 8-2) during the product development.

- **Acceptance Criteria**

The validation type and acceptance criteria is shown in the Table 8-1 below:

Table 8-1. Validation type and acceptance criteria

Validation Type	**Acceptance Criteria**
Average DICE	The average dice of testing data is higher than 0.8

- **Testing Data Information**

Table 8-2. Testing data information

Information of data	60 chest CTs
Sex	Male 37 Female 23
Age	[14, 35] : 5 [36, 69] : 41 [70, 86] : 14

- **Performance Testing Summary:**

The average dice on testing data set is 0.855, which is higher than 0.8. Meanwhile, the subgroup analysis shows that (Table 8-3) the performance of algorithm are consist in different subgroups.

Table 8-3. Subgroup performance test

Age	DICE
[14,35]	0.848
[36,69]	0.856
[70,86]	0.856
Gender	DICE
Female	0.856
Male	0.855

- **Standard Annotation Process**

For ground truth annotations, all ground truth are annotated by well-trained annotators. A threshold based interactive tool is used to generate initial rib mask, then annotators will refine the rib mask. After the first round annotation, they will check each other's annotation. At last, a senior clinical specialist will check and modify annotations to make sure the ground truth correct.

- **Testing & Training Data Independence**

The training data used for the training of the post-processing algorithm is independent of the data used to test the algorithm

Other Standards and Guidance

- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2016).
- ISO 14971 Medical devices - Application of risk management to medical devices (Edition 2.0, corrected version, 2007).
- IEC 62304 Medical device software - Software life cycle processes (Edition 1.1, 2015).

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above; the uOmnispace was found to have a safety and effectiveness profile that is similar to the predicate device and reference devices.

9. Substantially Equivalent Conclusion

The proposed device is equivalent to the predicate device with 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 devices.