April 22, 2026

Shanghai United Imaging Healthcare Co., Ltd.
Xin Gao
Regulatory Affairs Manager
No. 2258 Chengbei Rd. Jiading District
Shanghai, 201807
China

Re: K253077
Trade/Device Name: uOmnispace.MR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 22, 2026
Received: March 23, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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.

510(k) Number *(if known)*
K253077

Device Name
uOmnispace.MR

Indications for Use *(Describe)*
uOmnispace.MR is a software solution intended to be used for viewing, manipulating, evaluating and analyzing medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications:

The uOmnispace.MR Stitching is intended to create full-format images from overlapping MR volume data sets acquired at multiple stages.
The uOmnispace.MR Dynamic application is intended to provide a general post-processing tool for time course studies.
The uOmnispace.MR MRS (MR Spectroscopy) is intended to evaluate the molecule constitution and spatial distribution of cell metabolism. It provides a set of tools to view, process, and analyze the complex MRS data. This application supports the analysis for both SVS (Single Voxel Spectroscopy) and CSI (Chemical Shift Imaging) data.
The uOmnispace.MR MAPs application is intended to provide a number of arithmetic and statistical functions for evaluating dynamic processes and images. These functions are applied to the grayscale values of medical images.
The uOmnispace.MR Breast Evaluation application provides the user a tool to calculate parameter maps from contrast-enhanced time-course images.
The uOmnispace.MR Brain Perfusion application is intended to allow the visualization of temporal variations in the dynamic susceptibility time series of MR datasets.
The uOmnispace.MR Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating MR vascular images.
The uOmnispace.MR DCE analysis is intended to view, manipulate, and evaluate dynamic contrast-enhanced MRI images.
The uOmnispace.MR United Neuro is intended to view, manipulate, and evaluate MR neurological images.
The uOmnispace.MR Cardiac Function is intended to view, evaluate functional analysis of cardiac MR images.
The uOmnispace.MR Flow Analysis is intended to view, evaluate flow analysis of flow MR images.
The uOmnispace.MR Cardiac Perfusion is intended to view, process and analyze MR cardiac perfusion images.
The uOmnispace.MR Cardiac Viability is intended to view, process and analyze MR late gadolinium enhancement images.
The uOmnispace.MR Diffusion Analysis is intended to view, process and analyze MR diffusion images.
The uOmnispace.MR SWI+ is intended to view and generate susceptibility weighted images (SWI) and quantitative susceptibility mapping (QSM) images.
The uOmnispace.MR Multiplex Analysis is intended to generate and view multiple virtual contrast images.
The uOmnispace.MR ASL is intended to view, process and analyze MR arterial spin labeling (ASL) images.

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

K253077

1. Date of Preparation:

April 20, 2026

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
Position: Regulatory Affairs Specialist
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3. Identification of Proposed Device

Trade Name: uOmnispace.MR
Common Name: Medical Image Post-processing Software
Model(s): uOmnispace.MR

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: K233186
Device Name: uOmnispace.MR

Reference Device 1
510(k) Number: K213583

Device Name: Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems

Reference Device 2
510(k) Number: K213165
Device Name: Rapid

Reference Device 3
510(k) Number: K173467
Device Name: Advanced Diffusion Analysis (ADA) application

Reference Device 4
510(k) Number: K243122
Device Name: uMR Omega

Reference Device 5
510(k) Number: K193200
Device Name: uMR Omega

Reference Device 6
510(k) Number: K220332
Device Name: uMR Omega

Reference Device 7
510(k) Number: K211059
Device Name: CereFlow™ V1.2

5. Device Description

The uOmnispace.MR is a post-processing software based on the uOmnispace platform for viewing, manipulating, evaluating and analyzing MR images, can run alone or with other advanced commercially cleared applications.

This proposed device contains the following applications:

- uOmnispace.MR Stitching
- uOmnispace.MR Dynamic
- uOmnispace.MR MRS
- uOmnispace.MR MAPs
- uOmnispace.MR Breast Evaluation

- uOmnispace.MR Brain Perfusion
- uOmnispace.MR Vessel Analysis
- uOmnispace.MR DCE Analysis
- uOmnispace.MR United Neuro
- uOmnispace.MR Cardiac Function
- uOmnispace.MR Flow Analysis
- uOmnispace.MR Cardiac Perfusion
- uOmnispace.MR Cardiac Viability
- uOmnispace.MR Diffusion
- uOmnispace.MR SWI+
- uOmnispace.MR Multiplex Analysis
- uOmnispace.MR ASL

The modifications performed on the uOmnispace.MR (K233186) in this submission is due to the following changes:

- Add new features for Brain Perfusion,
- Add new applications: Cardiac Perfusion, Cardiac Viability, SWI+, Diffusion Analysis, Multiplex Analysis and ASL.

These modifications do not affect the intended use or alter the fundamental scientific technology of the device.

6. Indications for use

uOmnispace.MR is a software solution intended to be used for viewing, manipulating, evaluating and analyzing medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications:

- The uOmnispace.MR Stitching is intended to create full-format images from overlapping MR volume data sets acquired at multiple stages.
- The uOmnispace.MR Dynamic application is intended to provide a general post-processing tool for time course studies.
- The uOmnispace.MR MRS (MR Spectroscopy) is intended to evaluate the molecule constitution and spatial distribution of cell metabolism. It provides a set of tools to view, process, and analyze the complex MRS data. This application supports the analysis for both SVS (Single Voxel Spectroscopy) and CSI (Chemical Shift Imaging) data.
- The uOmnispace.MR MAPs application is intended to provide a number of arithmetic and statistical functions for evaluating dynamic processes and images. These functions are applied to the grayscale values of medical images.

- The uOmnispace.MR Breast Evaluation application provides the user a tool to calculate parameter maps from contrast-enhanced time-course images.
- The uOmnispace.MR Brain Perfusion application is intended to allow the visualization of temporal variations in the dynamic susceptibility time series of MR datasets.
- The uOmnispace.MR Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating MR vascular images.
- The uOmnispace.MR DCE analysis is intended to view, manipulate, and evaluate dynamic contrast-enhanced MRI images.
- The uOmnispace.MR United Neuro is intended to view, manipulate, and evaluate MR neurological images.
- The uOmnispace.MR Cardiac Function is intended to view, evaluate functional analysis of cardiac MR images.
- The uOmnispace.MR Flow Analysis is intended to view, evaluate flow analysis of flow MR images.
- The uOmnispace.MR Cardiac Perfusion is intended to view, process and analyze MR cardiac perfusion images.
- The uOmnispace.MR Cardiac Viability is intended to view, process and analyze MR late gadolinium enhancement images.
- The uOmnispace.MR Diffusion Analysis is intended to view, process and analyze MR diffusion images.
- The uOmnispace.MR SWI+ is intended to view and generate susceptibility weighted images (SWI) and quantitative susceptibility mapping (QSM) images.
- The uOmnispace.MR Multiplex Analysis is intended to generate and view multiple virtual contrast images.
- The uOmnispace.MR ASL is intended to view, process and analyze MR arterial spin labeling (ASL) images.

7. Summary of Technological Characteristics

The technology characteristics of uOmnispace.MR, reflected in this 510(k) submission are substantially equivalent to those of the predicate devices.
The following tables compare the main features, principles of operation, fundamental scientific technology and intended use of uOmnispace.MR when compared to the predicate devices.

Table 1 Substantial equivalent discussion for basic functions

Item	**Proposed Device** uOmnispace.MR	**Predicate Device** uOmnispace.MR	**Remark**
General			
Device Classification Name	Medical image management and processing system	Medical image management and processing system	Same
Product Code	QIH	QIH	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Device Class	II	II	Same
Classification Panel	Radiology	Radiology	Same
Advanced Application	Yes	Yes	Same
Indications for use	uOmnispace.MR is a software solution intended to be used for viewing, manipulating, evaluating and analyzing medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications: • The uOmnispace.MR Stitching is intended to create full-format images from overlapping MR volume data sets acquired at multiple stages. • The uOmnispace.MR Dynamic application is intended to provide a general	uOmnispace.MR is a software solution intended to be used for viewing, manipulating, evaluating and analyzing medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications: • The uOmnispace.MR Stitching is intended to create full-format images from overlapping MR volume data sets acquired at multiple stages. • The uOmnispace.MR Dynamic application is intended to provide a general	Substantial Equivalent Note 1

Item	Proposed Device uOmnispace.MR	Predicate Device uOmnispace.MR	Remark
	post-processing tool for time course studies. • The uOmnispace.MR MRS (MR Spectroscopy) is intended to evaluate the molecule constitution and spatial distribution of cell metabolism. It provides a set of tools to view, process, and analyze the complex MRS data. This application supports the analysis for both SVS (Single Voxel Spectroscopy) and CSI (Chemical Shift Imaging) data. • The uOmnispace.MR MAPs application is intended to provide a number of arithmetic and statistical functions for evaluating dynamic processes and images. These functions are applied to the grayscale values of medical images. • The uOmnispace.MR Breast Evaluation application provides the user a tool to calculate parameter maps from contrast-enhanced time-course images. • The uOmnispace.MR Brain Perfusion application is intended to allow the visualization of temporal variations in	post-processing tool for time course studies. • The uOmnispace.MR MRS (MR Spectroscopy) is intended to evaluate the molecule constitution and spatial distribution of cell metabolism. It provides a set of tools to view, process, and analyze the complex MRS data. This application supports the analysis for both SVS (Single Voxel Spectroscopy) and CSI (Chemical Shift Imaging) data. • The uOmnispace.MR MAPs application is intended to provide a number of arithmetic and statistical functions for evaluating dynamic processes and images. These functions are applied to the grayscale values of medical images. • The uOmnispace.MR Breast Evaluation application provides the user a tool to calculate parameter maps from contrast-enhanced time-course images. • The uOmnispace.MR Brain Perfusion application is intended to allow the visualization of temporal variations in	

Item	Proposed Device uOmnispace.MR	Predicate Device uOmnispace.MR	Remark
	the dynamic susceptibility time series of MR datasets. • The uOmnispace.MR Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating MR vascular images. • The uOmnispace.MR DCE analysis is intended to view, manipulate, and evaluate dynamic contrast-enhanced MRI images. • The uOmnispace.MR United Neuro is intended to view, manipulate, and evaluate MR neurological images. • The uOmnispace.MR Cardiac Function is intended to view, evaluate functional analysis of cardiac MR images. • The uOmnispace.MR Flow Analysis is intended to view, evaluate flow analysis of flow MR images. • The uOmnispace.MR Cardiac Perfusion is intended to view, process and analyze MR cardiac perfusion images.	the dynamic susceptibility time series of MR datasets. • The uOmnispace.MR Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating MR vascular images. • The uOmnispace.MR DCE analysis is intended to view, manipulate, and evaluate dynamic contrast-enhanced MRI images. • The uOmnispace.MR United Neuro is intended to view, manipulate, and evaluate MR neurological images. • The uOmnispace.MR Cardiac Function is intended to view, evaluate functional analysis of cardiac MR images. • The uOmnispace.MR Flow Analysis is intended to view, evaluate flow analysis of flow MR images.	

Item	Proposed Device uOmnispace.MR	Predicate Device uOmnispace.MR	Remark
	• The uOmnispace.MR Cardiac Viability is intended to view, process and analyze MR late gadolinium enhancement images. • The uOmnispace.MR Diffusion Analysis is intended to view, process and analyze MR diffusion images. • The uOmnispace.MR SWI+ is intended to view and generate susceptibility weighted images (SWI) and quantitative susceptibility mapping (QSM) images. • The uOmnispace.MR Multiplex Analysis is intended to generate and view multiple virtual contrast images. • The uOmnispace.MR ASL is intended to view, process and analyze MR arterial spin labeling (ASL) images.		

Table 2 Substantial equivalent discussion for Advanced Applications

Application	Function name	Proposed device uOmnispace.MR	Predicate Device uOmnispace.MR (K233186)	Remark
MR DCE Analysis	Motion Correction	Yes	Yes	Same
	Series Registration	Yes	Yes	Same

	Parametric Maps	Yes	Yes	Same
	ROI Analysis	Yes	Yes	Same
	Save, Filming and Report	Yes	Yes	Same
MR Breast Evaluation	Automatic Subtraction	Yes	Yes	Same
	Motion Correction	Yes	Yes	Same
	TIC Analysis	Yes	Yes	Same
	Background Removal	Yes	Yes	Same
	Parameter Map Calculation	Yes	Yes	Same
	Save, Filming and Report	Yes	Yes	Same
MR Stitching	Automatic Stitching	Yes	Yes	Same
	Manual Stitching	Yes	Yes	Same
	Normalization	Yes	Yes	Same
	Sharp/Smooth	Yes	Yes	Same
	Save, Filming and Report	Yes	Yes	Same
MR Vessel Analysis	Automatic Centerline Extraction	Yes	Yes	Same
	Vascular Stenosis Analysis	Yes	Yes	Same
	Optimized Vascular Displaying	Yes	Yes	Same
	Save, Filming and Report	Yes	Yes	Same
MR Dynamic	Background Removal	Yes	Yes	Same
	Motion Correction	Yes	Yes	Same
	TIC Analysis	Yes	Yes	Same
	Statistic Table	Yes	Yes	Same
	DCE and DSC Analysis	Yes	Yes	Same
	Save, Filming and Report	Yes	Yes	Same
MR MAPs	Background Removal	Yes	Yes	Same
	T1, T2/R2, T2*/R2*, T1rho Calculation	Yes	Yes	Same

	ADC and eADC Calculation	Yes	Yes	Same
	TIC Analysis	Yes	Yes	Same
	Statistic Table	Yes	Yes	Same
	Save, Filming and Report	Yes	Yes	Same
MR United Neuro	Motion Correction	Yes	Yes	Same
	Functional Activation Calculation	Yes	Yes	Same
	Diffusion Parameter Analysis	Yes	Yes	Same
	Adjust Display Parameter	Yes	Yes	Same
	Fusion	Yes	Yes	Same
	Fiber Tracking	Yes	Yes	Same
	Time-Intensity Curve	Yes	Yes	Same
	ROI Analysis	Yes	Yes	Same
	MR Segmentation	Yes	Yes	Same
	Save, Filming and Report	Yes	Yes	Same
MR Cardiac Function	LV&RV Contour Segmentation	Yes	Yes	Same
	LAX Extent Definition	Yes	Yes	Same
	Parameter Calculation	Yes	Yes	Same
	BSA Standardized	Yes	Yes	Same
	Polar Maps	Yes	Yes	Same
	Volume Curve	Yes	Yes	Same
	Save, Filming and Report	Yes	Yes	Same
MR Flow Analysis	Contour Segmentation	Yes	Yes	Same
	Propagate Contour	Yes	Yes	Same
	Doppler Map	Yes	Yes	Same
	Parameters Calculation	Yes	Yes	Same
	Flow Curve	Yes	Yes	Same
	Save, Filming and Report	Yes	Yes	Same

MR MRS	Single-Voxel Spectrum Data Analysis	Yes	Yes	Same
	Chemical Shift Imaging Data Analysis	Yes	Yes	Same
	Protocol Management	Yes	Yes	Same
	Protocol Editing	Yes	Yes	Same
	Save, Filming and Report	Yes	Yes	Same

Table 3 Substantial equivalent discussion for Brain Perfusion

Application	**Function name**	**Proposed Device** uOmnispace.MR	**Predicate Device** uOmnispace.MR (K233186)	**Reference Device#1** Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems (K213583)	**Reference Device#2** Rapid (K213165)	**Remark**
MR Brain Perfusion	Motion Correction	Yes	Yes	/	/	Same
	Background Removal	Yes	Yes	/	/	Same
	Define Arterial Input Function (AIF)	Yes	Yes	/	/	Same
	Parametric Mapping Calculation	Yes	Yes	Yes	Yes	Substantial Equivalent Note 2
	Mismatch	Yes	/	/	Yes	Same
	TIC Analysis	Yes	Yes	/	/	Same
	Save, Filming and Report	Yes	Yes	/	/	Same

Table 4 Substantial equivalent discussion for Cardiac Perfusion

Application	**Function name**	**Proposed device** uOmnispace.MR	**Predicate Device** uOmnispace.MR (K233186)	**Reference Device#1** Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems (K213583)	**Remark**
MR Cardiac Perfusion	Motion Correction	Yes	/	Yes	Same
	Contour Segmentation	Yes	Yes	/	Same
	Parameter Calculation	Yes	/	Yes	Same
	Polar Maps	Yes	Yes	/	Same
	TIC Analysis	Yes	Yes	/	Same
	Save, Filming and Report	Yes	Yes	/	Same

Table 5 Substantial equivalent discussion for MR Cardiac Viability

Application	**Function name**	**Proposed device** uOmnispace.MR	**Predicate Device** uOmnispace.MR (K233186)	**Reference Device#1** Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems (K213583)	**Remark**
MR Cardiac Viability	Contour Segmentation	Yes	Yes	/	Same
	Enhancement Segmentation	Yes	/	Yes	Same
	Parameter Calculation	Yes	/	Yes	Same
	Polar Maps	Yes	Yes	/	Same
	Save, Filming and Report	Yes	Yes	/	Same

Table 6 Substantial equivalent discussion for MR Diffusion Analysis

Application	**Function name**	**Proposed Device** uOmnispace.MR	**Predicate Device** uOmnispace.MR (K233186)	**Reference Device #3** Advanced Diffusion Analysis (ADA) application (K173467)	**Remark**
MR Diffusion Analysis	Motion Correction	Yes	Yes	/	Same
	Parametric Mapping Calculation	Yes	Yes	Yes	Substantial Equivalent Note 3
	ROI Analysis	Yes	Yes	/	Same
	Save, Filming and Report	Yes	Yes	/	Same

Table 7 Substantial equivalent discussion for MR SWI+

Application	**Function name**	**Proposed Device** uOmnispace.MR	**Predicate Device** uOmnispace.MR (K233186)	**Reference Device#4** uMR Omega (K243122)	**Reference Device#5** uMR Omega (K193200)	**Remark**
MR SWI+	Virtual TE	Yes	/	/	Yes	Substantial Equivalent Note 4
	Parametric Mapping Calculation	Yes	Yes	Yes	/	Substantial Equivalent Note 5

	Save, Filming and Report	Yes	Yes	/		Same

Table 8 Substantial equivalent discussion for MR Multiplex Analysis

Application	**Function name**	**Proposed device** uOmnispace.MR	**Predicate Device** uOmnispace.MR (K233186)	**Reference Device#3** uMR Omega (K243122)	**Remark**
MR Multiplex Analysis	Virtual contrast images generation	Yes	/	Yes	Substantial Equivalent Note 6
	ROI Analysis	Yes	Yes	/	Same
	Save, Filming and Report	Yes	Yes	/	Same

Table 9 Substantial equivalent discussion for MR ASL

Application	**Function name**		**Proposed Device** uOmnispace.MR	**Predicate Device** uOmnispace.MR (K233186)	**Reference Device#6** uMR Omega (K220332)	**Reference Device#7** CereFlow™ V1.2 （K211059）	**Remark**
MR ASL	Motion Correction		Yes	Yes	/	/	Same
	Background Removal		Yes	/	/	Yes	Same
	Parametric Mapping Calculation	sPLD model: CBF, MeanCBF	/	/	Yes	/	Substantial Equivalent Note 7

		mPLD model: CBF and ATT	/	/	/	Yes	Substantial Equivalent Note 8
	TIC Analysis		Yes	Yes		/	Same
	Save, Filming and Report		Yes	Yes		/	Same

Note 1: Compared to the predicate device, the proposed device includes six new applications, which are discussed in the following sections. This difference will not impact the safety and effectiveness of the device.

Note 2: Compared to the predicate device, the proposed device adds parametric maps rCBV_uncorr, rCBV_corr, K1, K2, R2 and Tmax. Among these, rCBV_uncorr, rCBV_corr, K1, K2, R2 are functionally equivalent to those of reference device K213583, and Tmax is functionally equivalent to that of reference device K213165. Verification tests demonstrate that Brain Analysis yields accurate parametric maps. Therefore, this difference will not impact the safety and effectiveness of the device.

Note 3: The proposed device generates DKI model-derived parametric maps MD, FA, AD and RD, which are the same as ADC, FA, E1, E2E3 respectively in United Neuro of the predicate device. The underlying calculation principles for these parametric maps are the same as those of the predicate device. In addition, IVIM and sDKI model-derived parametric maps (sADC, F, D, Dstar, MD and MK) are functionally equivalent to D, f, Dstar, K, as generated by different models of reference device K173467. rBF is the product of F and Dstar. Verification tests demonstrate that diffusion analysis yields accurate parametric maps. Therefore, this difference will not impact the safety and effectiveness of the device.

Note 4: Compared to the predicate device, the proposed device adds a virtual TE function. This function generates SWI images based on user-set TE values, and its calculation method is the same as that used in reference device K193200. Verification tests demonstrate that SWI+ yields accurate SWI images with different TE values. Therefore, this difference will not impact the safety and effectiveness of the device.

Note 5: Compared to the predicate device, the proposed device provides the same R2star as MAPS. In addition, the proposed device provides new image QSM. QSM is the same as that from reference device K243122.Verification tests demonstrate that SWI+ yields accurate QSM calculation. Therefore, this difference will not impact the safety and effectiveness of the device.

Note 6: Compared to the predicate device, the proposed device adds a function to generate images with multiple contrast by adjusting parameters. The function is substantially equivalent to that of reference device K243122 and use the same calculation principle. Verification tests demonstrate that Multiplex Analysis yields accurate virtual contrast images. Therefore, this difference will not impact the safety and effectiveness of the device.

Note 7: Compared to the predicate device, the proposed device adds CBF and MeanCBF from sPLD model. Of which, CBF is the same as that from reference device K220332, and MeanCBF is the average map of CBF maps calculated from multiple single-PLD data. Verification tests demonstrate that ASL yields accurate CBF. Therefore, this difference will not impact the safety and effectiveness of the device.

Note 8: Compared to the predicate device, the proposed device adds CBF and ATT from mPLD model. Of which, CBF and ATT are semi-quantitative quantification of ASL data and are the same as those from reference device K211059. Verification tests demonstrate that ASL yields accurate CBF and ATT. Therefore, this difference will not impact the safety and effectiveness of the 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
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
Non-clinical performance testing was conducted to verify the features described in this premarket submission of the proposed device. Testing included both technical performance evaluation (quantitative comparison with predicate/reference devices) and clinical image evaluation (qualitative assessment by two U.S. board-certified radiologists using a 5-point Likert Scale comparing the proposed device and predicate/reference devices; a score of ≥3 was clinically acceptable). The specific tests conducted, test methods, and acceptance criteria are summarized below.

(1) MR Brain Perfusion
(a) Leakage Correction Parametric Maps (rCBV_uncorr, rCBV_corr, K1, K2, R^2): Parametric maps were compared with those from the reference device (K213583) using ICC (Intraclass Correlation Coefficient) and clinical image evaluation. Acceptance Criteria: ICC > 0.75, clinical acceptability rate ≥ 95%. Results: rCBV_uncorr, ICC = 0.998, the mean difference (bias) was -0.20 (95% LoA: -36.32 to 35.92); rCBV_corr, ICC = 0.999, the mean difference (bias) was -0.79 (95% LoA: -31.93 to 30.35); K1, ICC = 0.999, the mean difference (bias) was -0.32 (95% LoA: -30.74 to 30.10); K2, ICC = 0.997, the mean difference (bias) was 3.57 (95% LoA: -55.31 to 62.45); R^2 was assessed by analytical justification as a derived goodness-of-fit metric, and no separate standalone verification was

required; the clinical acceptability rate for all Leakage Correction Parametric Maps was 100%.
(b) Tmax Calculation: Tmax maps were compared with those from the reference device (K213165) using ICC and clinical image evaluation. Acceptance Criteria: ICC > 0.75, clinical acceptability rate ≥ 95%. Results: ICC=0.9942, the mean difference (bias) was -0.03 sec (95% LoA: -0.34 to 0.27 sec), clinical acceptability rate = 100%.

(c) Mismatch: ROI_Tmax and ROI_ADC volumes were compared with those from the reference device (K213165) using ICC and clinical image evaluation, Acceptance Criteria: ICC > 0.75, clinical acceptability rate ≥ 95%. Results: ROI_Tmax ICC=0.9953, the mean difference (bias) was 1.1 mL (95% LoA: -6.8 to 9.0 mL), clinical acceptability rate = 100%; ROI_ADC ICC=0.9946, the mean difference (bias) was -0.9 ml (95% LoA: -9.0 to 7.2 ml), clinical acceptability rate = 100%.

(2) MR Cardiac Perfusion
(a) Motion Correction: The motion correction function is implemented in the same manner as the reference device (K213583). Accuracy was evaluated by computing the Dice coefficient of myocardial regions between corrected image pairs. Acceptance Criteria: Average Dice coefficient > 0.87. Result: Average Dice coefficient =0.90
(b) Parameter Calculation: The parameters are defined and calculated in the same manner as the reference device (K213583). Accuracy was verified by comparing with manually calculated ground truth values using RMSE. Acceptance Criteria: RMSE < 0.01. Result: RMSE=0.00;

(3) MR Cardiac Viability
Parameter Calculation: The parameters are defined and calculated in the same manner as the reference device (K213583). Accuracy was verified using digital phantom datasets with known ground truth, and the relative error (RE) was calculated. Acceptance Criteria: RE < 0.01.Result: RE < 0.01 for all evaluated cases.

(4) MR Diffusion Analysis
(a) Motion Correction: The motion correction function is implemented in the same manner as the predicate device (K233186). Accuracy was evaluated using clinical data with real patient motion and simulated motion data. NCC (Normalized Cross Correlation) was used for real-motion data; mTRE was used for simulated-motion data. Acceptance Criteria: Statistically significant increase in NCC ($p < 0.05$); mTRE less than voxel diagonal distance. Results: NCC value after motion correction was higher than the NCC value before motion correction ($p < 0.05$); mTRE was less than voxel diagonal distance.
(b) Parametric Mapping Calculation (sADC, D, Dstar, F, rBF, MD, MK, AD, RD, FA): Clinical evaluation compared with predicate device (K233186) and reference device (K173467) for IVIM, sDKI and DKI models. Acceptance Criteria: clinical acceptability rate ≥ 95%. Results: the clinical acceptability rate for all maps was 100%.

(5) MR SWI+

(a) SWI (Virtual TE): SWI maps were compared with those from reference device (K193200) using ICC and clinical image evaluation. Acceptance Criteria: ICC > 0.75, clinical acceptability rate ≥ 95%. Results: ICC=0.9968, the mean difference (bias) was 1.2 (95% LoA: -3.3 to 5.7), clinical acceptability rate = 100%;
(b) QSM: QSM maps were compared with those from reference device (K243122) using ICC and clinical image evaluation. Acceptance Criteria: ICC > 0.75, clinical acceptability rate ≥ 95%. Results: ICC=0.9906, the mean difference (bias) was 0.3 ppb (95% LoA: -4.6 to 5.2 ppb), clinical acceptability rate = 100%;
(c) R2star: R2star maps were compared with those from the predicate device MAPs application (K233186) using RMSE. Acceptance Criteria: RMSE < 0.01. Result: RMSE=0.00.

(6) MR Multiplex Analysis
Virtual Contrast Images Generation: The function of Virtual contrast images Generation is substantially equivalent to that of reference device K243122 and use the same calculation principle. Accuracy was evaluated by two U.S. board-certified radiologists comparing diagnostic quality and radiologic findings with conventional MR images. Acceptance Criteria: Diagnostic acceptable rate ≥ 98% with lower limit of the two-sided 95% confidence interval > 85% for pathology cases; clinical acceptability rate = 100% for healthy volunteers. Results: diagnostic acceptable rate =100%with lower limit of the two-sided 95% confidence interval was 88.43%; clinical acceptability rate = 100%.

(7) MR ASL
(a) Motion Correction: The motion correction function is implemented in the same manner as the predicate device (K233186). Accuracy was evaluated using clinical data with real motion and simulated motion data. SSIM (Structural Similarity Index Measure) was used for real-motion data; mTRE was used for simulated-motion data. Acceptance Criteria: Statistically significant increase in SSIM ($p < 0.05$); mTRE less than voxel diagonal distance. Results: SSIM value after motion correction was higher than the SSIM value before motion correction ($p < 0.05$); mTRE was less than voxel diagonal distance.
(b) Registration: The registration function is implemented in the same manner as the predicate device (K233186). Accuracy was assessed using mTRE with predefined spatial transformations. Acceptance Criteria: mTRE less than voxel diagonal distance. Result: mTRE was less than voxel diagonal distance.
(c) Background Removal: Brain masks were compared with those from reference device (K211059) using the Dice coefficient. Acceptance Criteria: Dice coefficient > 0.9. Result: Average Dice coefficient = 0.925.
(d) Parametric Map Calculation – Single PLD: The CBF calculation method is algorithmically equivalent to the reference device (K220332). Accuracy was verified by comparing with the reference result using ICC (Intraclass Correlation Coefficient), acceptance criteria: ICC > 0.75, result ICC=0.9999, the mean difference (bias) was 0.00 mL/100g/min (95% LoA: -0.23 to 0.23 mL/100g/min).

(e) Parametric Map Calculation – Multi-PLD: CBF and ATT maps were compared with those from reference device (K211059) using clinical image evaluation. Acceptance Criteria: clinical acceptability rate ≥ 95%. Result: clinical acceptability rate =100%.

All test results met the predefined pass/fail criteria, demonstrating safety and effectiveness of the proposed device.

Other Standards and Guidance

- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2023e).
- 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).
- Cybersecurity in Medical Devices Quality System Considerations and Content of Premarket Submissions.
- Content of Premarket Submissions for Device Software Functions.

Summary

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

9. Substantially Equivalent (SE) 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.