Shanghai United Imaging Healthcare Co., Ltd.
Gao Xin
Official Correspondent
No. 2258 Chengbei Road. Jiading District
Shanghai, 201807
China

April 17th, 2024

Re: K233186
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 7, 2024
Received: March 7, 2024

Dear Gao Xin:

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.

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,

Ningzhi Li -S

for
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.

Submission Number *(if known)*

K233186

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 postprocessing 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.

■ MR 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.

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

K233186

1. Date of Preparation:

September 26, 2023

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: Medical Image Post-processing Software
Common Name: Medical image management and processing system
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

Device Classification Name	Medical image management and processing system
510(K) Number	K192601
Device Name	uWS-MR
Manufacturer	Shanghai United Imaging Healthcare Co., Ltd.
Regulation Number	21 CFR 892.2050

Classification Product Code	QIH
Device Classification	Class II
Classification Panel	Radiology
Intended use	uWS-MR is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions.

Reference Device #1

Device Classification Name	Magnetic resonance diagnostic device
510(K) Number	K220332
Device Name	uMR Omega with uWS-MR-MRS
Manufacturer	Shanghai United Imaging Healthcare Co., Ltd.
Regulation Number	21 CFR 892.1000
Classification Product Code	LNH
Device Classification	Class II
Classification Panel	Radiology
Intended use	uWS-MR is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions.

Reference Device #2

Device Classification Name	Picture Archiving and Communications System
510(K) Number	K141480
Device Name	cvi42
Manufacturer	Circle Cardiovascular Imaging Inc
Regulation Number	21 CFR 892.2050
Classification Product Code	LLZ
Device Classification	Class II
Classification Panel	Radiology
Intended use	cvi 42 vascular add-on is software application for evaluating cardiovascular images in a DICOM Standard format. cvi 42 has a graphical user interface which allows users to qualitatively and quantitatively analyze cardiac CT & MR images.

Reference Device #3

Device Classification Name	Magnetic resonance diagnostic device
510(K) Number	K230152
Device Name	uMR Omega
Manufacturer	Shanghai United Imaging Healthcare Co., Ltd.
Regulation Number	21 CFR 892.1000
Classification Product Code	LNH
Device Classification	Class II
Classification Panel	Radiology
Intended use	The uMR Omega system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces sagittal, transverse, coronal, and oblique cross sectional images, and spectroscopic images, and that display internal anatomical structure and/or function of the head, body and extremities.

Reference Device #4

Device Classification Name	Picture archiving and communication system
510(K) Number	K113456
Device Name	READY View
Manufacturer	GE Healthcare
Regulation Number	21 CFR 892.2050
Classification Product Code	LLZ
Device Classification	Class II
Classification Panel	Radiology
Intended use	READY View is a image analysis software that allows the user to process dynamic or functional volumetric data and to generate maps that display changes in image intensity aver time, echo time, lb-vague (Diffusion imaging) and frequency (Spectroscopy). The combination of acquired images, reconstructed images, calculated parametric images, tissue segmentation, annotations and measurement performed by the clinician allows multi-parametric analysis and may provide clinically relevant information for diagnosis.

5. Device Description

The uOmnispace.MR is a post-processing software based on the uOmnispace platform (cleared in K230039) 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 Analysis
- uOmnispace.MR Flow Analysis

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

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** uWS-MR (K192601)	**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.	uWS-MR is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications: • The MR Stitching is intended to create full-format images from overlapping MR volume data sets acquired at multiple stages.	Substantial Equivalent Note 1

Item	Proposed Device uOmnispace.MR	Predicate Device uWS-MR (K192601)	Remark
	• 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	• The Dynamic application is intended to provide a general post-processing tool for time course studies. • 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 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 MR Breast Evaluation application provides the user a tool to calculate	

Item	Proposed Device uOmnispace.MR	Predicate Device uWS-MR (K192601)	Remark
	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.	parameter maps from contrast-enhanced time-course images. • The Brain Perfusion application is intended to allow the visualization of temporal variations in the dynamic susceptibility time series of MR datasets. • MR Vessel Analysis is intended to provide a tool for viewing, manipulating, and evaluating MR vascular images. • The DCE analysis is intended to view, manipulate, and evaluate dynamic contrast-enhanced MRI images. • The United Neuro is intended to view, manipulate, and evaluate MR neurological images. • The MR Cardiac Analysis application is intended to be used for viewing, post-processing and quantitative	

Item	Proposed Device uOmnispace.MR	Predicate Device uWS-MR (K192601)	Remark
	• The uOmnispace.MR Flow Analysis is intended to view, evaluate flow analysis of flow MR images.	evaluation of cardiac magnetic resonance data.	

Table 2 Substantial equivalent discussion for Advanced Applications

Application	Function name	Proposed device uOmnispace.MR	Predicate Device uWS-MR (K192601)	Reference Device#1 uMR Omega with uWS-MR-MRS (K220332)	Reference Device#2 cvi42 (K141480)	Reference Device#3 uMR Omega (K230152)	Reference Device#4 READY View (K113456)	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 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	/	/	/	/	Same
	TIC 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:WO, WI, TTP, PEI and MSI	Yes	Yes	/	/	/	/	Same
	Parameter Map Calculation: SER	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*	Yes	Yes	/	/	Yes	/	Same
	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	/	Yes	/	/	Substantial equivalent Note 2
	Propagate Contour	Yes	Yes	/	/	/	/	Same
	Doppler Map	Yes	Yes	/	/	/	/	Same
	Parameters Calculation	Yes	Yes	/	/	/	/	Substantial equivalent Note 3
	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

Note 1: Compared with the predicate device, Cardiac Function and Flow Analysis are stated separately in this submission rather than as a whole Cardiac Analysis package. There is no impact on the safety and this change is considered minor and will only improve the workflow of uOmnispace.MR. Therefore, there would be no clinically significant difference in the safety and clinical performance of the device.
Note 2: For Flow Analysis, user can perform semi-automatic contour segmentation in addition to only manual segmentation in K192601. There is no impact on the safety and this change in algorithm is considered minor and will only improve the function of uOmnispace.MR, therefore there would be no clinically significant difference in the safety and clinical performance of the device.
Note 3: For Flow Analysis, there are two more output parameters (mean pressure gradient and peak pressure gradient). There is no impact on the safety and this change is considered minor and will only improve the function of uOmnispace.MR, therefore there would be no clinically significant difference in the safety and clinical performance 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 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 to satisfy the recommended documentation for basic documentation. These documentations include:

- Software Description
- Device Hazard Analysis
- Software Requirements Specification (SRS)
- 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

- Performance Evaluation Report for applications

Performance tests were conducted to assess the algorithms of the uOmnispace.MR. These tests have been performed to assess the algorithms of the Subject Device. The results of all conducted testing were found acceptable and do not raise any new issues of safety or effectiveness. All testing data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Device that is currently marketed for the same intended use.

The performance functionality of new parameters or algorithms for uOmnispace.MR has been tested and validated, including SER (signal enhancement ratio) parameter in MR Breast Evaluation, T1rho parameter in MR MAPs, as well as semi-automatic contour segmentation for Contour Segmentation function, mean pressure gradient and peak pressure gradient parameters for Parameters Calculation function in MR Flow Analysis.

In this submission, LV&RV Contour Segmentation is an AI algorithm, which is cleared in K192601.

To validate the uOmnispace.MR software from a clinical perspective, the deep learning-based *Automatic ventricular segmentation Algorithm* for the LV&RV Contour Segmentation feature in MR Cardiac Function contained in the product underwent a scientific evaluation. The results of clinical data-based software validation for the proposed device demonstrated high consistency in comparison to the predicate device.

1. Automatic ventricular segmentation Algorithm

The performance testing for deep learning-based Automatic ventricular segmentation Algorithm was performed on 114 subjects (data shown in the Table 1 below) during the product development.

- **Acceptance Criteria**

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

Validation Type	Acceptance Criteria
Dice	To evaluate the proposed device of automatic ventricular segmentation, we compared the results with those of the cardiac function application of predicate device. The Sørensen–Dice coefficient is used to evaluate consistency. If dice>0.95, it is considered consistent between the two devices.

- **Testing Data Information**

Table 1 Testing data information

Information of data	114 samples from 114 different patients
Gender	Male: 35 Female:20 Unknown: 59
Age	[14, 25]: 5 (25, 40]: 12 (40, 60]: 22 (60, 79]: 13 Unknown: 62

Ethnicity	Europe: 50 Asia: 53 USA: 11
Manufacturer	UIH: 58 GE: 2 Philips: 2 Siemens: 52
Magnetic Field	1.5T: 23 3.0T: 41 Unknown: 50

- **Performance Testing Summary**

The dice between the proposed and predicate device is 1.00 and shows the high consistency between the two devices.

Gender	Average dice
Female	1.00
Male	1.00
Unknown	1.00
Age	Average dice
[14, 25]	1.00
(25, 40]	1.00
(40, 60]	1.00
(60, 79]	1.00
Ethnicity	Average dice
Europe	1.00
Asia	1.00
USA	1.00
Manufacturer	Average dice
UIH	1.00
GE	1.00
Philips	1.00
Siemens	1.00
Magnetic Field	Average dice
1.5T	1.00
3.0T	1.00
Unknown	1.00

- **Standard Annotation Process**

As for the training ground truth, it was manually drawn on short axis slices in diastole and systole by two cardiologists with more than 10 years of experience each.

In details, manual tracing of the cardiac was performed by an experienced user. The validation of these contours was done by two independent expert (more than 10

years) in this domain. If there is a disagreement, a consensus between the experts was done.

- **Testing & Training Data Independence**

The training data used for the training of the cardiac ventricular segmentation 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.MR was found to have a safety and effectiveness profile that is similar to the predicate device and reference devices.

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 and reference devices.