May 14, 2025

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

Re: K242624
Trade/Device Name: Medical Image Post-processing Software (uOmnispace.CT)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: April 3, 2025
Received: April 3, 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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

k242624

Device Name

Medical Image Post-processing Software (uOmnispace.CT)

Indications for Use *(Describe)*

uOmnispace.CT is a software 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.CT Colon Analysis application is intended to provide the user a tool to enable easy visualization and efficient evaluation of CT volume data sets of the colon.

 The uOmnispace.CT Dental Application is intended to provide the user a tool to reconstruct panoramic and paraxial views of jaw.

 The uOmnispace.CT Lung Density Analysis application is intended to segment pulmonary, lobes, and airway, providing the user quantitative parameters, structure information to evaluate the lung and airway.

 The uOmnispace.CT Lung Nodule application is intended to provide the user a tool for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies.

 The Vessel Analysis application is intended to provide a tool for viewing, manipulating, and evaluating CT vascular images.

 The uOmnispace.CT Brain Perfusion application is intended to calculate the parameters such as: CBV, CBF, etc. in order to analyze functional blood flow information about a region of interest (ROI) in brain.

 The uOmnispace.CT Heart application is intended to segment heart and extract coronary artery. It also provides analysis of vascular stenosis, plaque and heart function.

 The uOmnispace.CT Calcium Scoring application is intended to identify calcifications and calculate the calcium score.

 The uOmnispace.CT Dynamic Analysis application is intended to support visualization of the CT datasets over time with the 3D/4D display modes.

 The uOmnispace.CT Bone Structure Analysis application is intended to provide visualization and labels for the ribs and spine, and support batch function for intervertebral disk.

 The uOmnispace.CT Liver Evaluation application is intended to provide processing and visualization for liver segmentation and vessel extraction. It also provides a tool for the user to perform liver separation and residual liver segments evaluation.

 The uOmnispace.CT Dual Energy is a post-processing software package that accepts UIH CT images acquired using different tube voltages and/or tube currents of the same anatomical location. The Dual Energy application is intended to provide information on the chemical composition of the scanned body materials and/or contrast agents. Additionally, it enables images to be generated at multiple energies within the available spectrum.

 The uOmnispace.CT Cardiovascular Combined Analysis is an image analysis software package for evaluating contrast enhanced CT images. The CT Cardiovascular Combined Analysis is intended to analyze vascular and cardiac structures.It can be used in the qualitative and quantitative for the analysis of head-neck, abdomen, multi-body part combined, TAVR (Transcatheter Aortic Valve Replacement) CT data as input for the planning of cardiovascular procedures.

 The uOmnispace.CT Body Perfusion is intended to analyze blood flow information of dynamic CT

images, by providing various perfusion-related parameters of the body parts.

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:

August 30, 2024

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
Tel: +86-021-67076888-5386
Fax: +86-021-67076889
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3. Identification of Proposed Device

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

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: K233209
Device Name: uOmnispace.CT

Reference Device
510(k) Number: K193289

Device Name: FastStroke, CT Perfusion 4D

5. Device Description

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

uOmnispace.CT contains the following applications:

- uOmnispace.CT Calcium Scoring
- uOmnispace.CT Lung Nodule
- uOmnispace.CT Colon Analysis
- uOmnispace.CT Lung Density Analysis
- uOmnispace.CT Dental Application
- uOmnispace.CT Bone Structure Analysis
- uOmnispace.CT Dual Energy
- uOmnispace.CT Vessel Analysis
- uOmnispace.CT Heart
- uOmnispace.CT Brain Perfusion
- uOmnispace.CT Dynamic Analysis
- uOmnispace.CT Liver Evaluation
- uOmnispace.CT Cardiovascular Combined Analysis
- uOmnispace.CT Body Perfusion

The modifications performed on the uOmnispace.CT (K233209) in this submission is due to the following changes that include:

- Add new application of Body Perfusion.
- Extend intended patient population for some applications
- Introduce deep-learning algorithm in applications of Lung Density Analysis, Vessel Analysis, Heart, Liver Evaluation and Cardiovascular Combined Analysis.

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

6. Indications for use

uOmnispace.CT is a software 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.CT Colon Analysis application is intended to provide the user a tool to enable easy visualization and efficient evaluation of CT volume data sets of the colon.
- The uOmnispace.CT Dental Application is intended to provide the user a tool to reconstruct panoramic and paraxial views of jaw.

- The uOmnispace.CT Lung Density Analysis application is intended to segment pulmonary, lobes, and airway, providing the user quantitative parameters, structure information to evaluate the lung and airway.
- The uOmnispace.CT Lung Nodule application is intended to provide the user a tool for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies.
- The uOmnispace.CT Vessel Analysis application is intended to provide a tool for viewing, manipulating, and evaluating CT vascular images.
- The uOmnispace.CT Brain Perfusion application is intended to calculate the parameters such as: CBV, CBF, etc. in order to analyze functional blood flow information about a region of interest (ROI) in brain.
- The uOmnispace.CT Heart application is intended to segment heart and extract coronary artery. It also provides analysis of vascular stenosis, plaque and heart function.
- The uOmnispace.CT Calcium Scoring application is intended to identify calcifications and calculate the calcium score.
- The uOmnispace.CT Dynamic Analysis application is intended to support visualization of the CT datasets over time with the 3D/4D display modes.
- The uOmnispace.CT Bone Structure Analysis application is intended to provide visualization and labels for the ribs and spine, and support batch function for intervertebral disk.
- The uOmnispace.CT Liver Evaluation application is intended to provide processing and visualization for liver segmentation and vessel extraction. It also provides a tool for the user to perform liver separation and residual liver segments evaluation.
- The uOmnispace.CT Dual Energy is a post-processing software package that accepts UIH CT images acquired using different tube voltages and/or tube currents of the same anatomical location. The Dual Energy application is intended to provide information on the chemical composition of the scanned body materials and/or contrast agents. Additionally, it enables images to be generated at multiple energies within the available spectrum.
- The uOmnispace.CT Cardiovascular Combined Analysis is an image analysis software package for evaluating contrast enhanced CT images. The CT Cardiovascular Combined Analysis is intended to analyze vascular and cardiac structures.It can be used in the qualitative and quantitative for the analysis of head-neck, abdomen, multi-body part combined, TAVR (Transcatheter Aortic Valve Replacement) CT data as input for the planning of cardiovascular procedures.
- The uOmnispace.CT Body Perfusion is intended to analyze blood flow information of dynamic CT images, by providing various perfusion-related parameters of the body parts.

7. Summary of Technological Characteristics

The technology characteristics of uOmnispace.CT, 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.CT when compared to the predicate devices.

Item	Proposed Device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	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
Intended Use	uOmnispace.CT is a software 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.CT Colon Analysis application is intended to provide the user a tool to enable easy visualization and efficient evaluation of CT volume data sets of the colon. • The uOmnispace.CT Dental application is intended to provide the user a tool to reconstruct panoramic and paraxial views of jaw. • The uOmnispace.CT Lung Density Analysis application is intended to segment pulmonary, lobes, and airway, providing the user quantitative parameters, structure	uOmnispace.CT is a software 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.CT Colon Analysis application is intended to provide the user a tool to enable easy visualization and efficient evaluation of CT volume data sets of the colon. • The uOmnispace.CT Dental application is intended to provide the user a tool to reconstruct panoramic and paraxial views of jaw. • The uOmnispace.CT Lung Density Analysis application is intended to segment pulmonary, lobes, and airway, providing the user quantitative parameters, structure	Substantial Equivalence The proposed device includes one more application than the predicate device, which is discussed in the following sections. This difference will not impact the safety and effectiveness of the device.

	information to evaluate the lung and airway. • The uOmnispace.CT Lung Nodule application is intended to provide the user a tool for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. • The uOmnispace.CT Vessel Analysis application is intended to provide a tool for viewing, manipulating, and evaluating CT vascular images. • The uOmnispace.CT Brain Perfusion application is intended to calculate the parameters such as: CBV, CBF, etc. in order to analyze functional blood flow information about a region of interest (ROI) in brain. • The uOmnispace.CT Heart application is intended to segment heart and extract coronary artery. It also provides analysis of vascular stenosis, plaque and heart function. • The uOmnispace.CT Calcium Scoring application is intended to identify calcifications and calculate the calcium score.	information to evaluate the lung and airway. • The uOmnispace.CT Lung Nodule application is intended to provide the user a tool for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. • The uOmnispace.CT Vessel Analysis application is intended to provide a tool for viewing, manipulating, and evaluating CT vascular images. • The uOmnispace.CT Brain Perfusion application is intended to calculate the parameters such as: CBV, CBF, etc. in order to analyze functional blood flow information about a region of interest (ROI) in brain. • The uOmnispace.CT Heart application is intended to segment heart and extract coronary artery. It also provides analysis of vascular stenosis, plaque and heart function. • The uOmnispace.CT Calcium Scoring application is intended to identify calcifications and calculate the calcium score.	

	• The uOmnispace.CT Dynamic Analysis application is intended to support visualization of the CT datasets over time with the 3D/4D display modes. • The uOmnispace.CT Bone Structure Analysis application is intended to provide visualization and labels for the ribs and spine, and support batch function for intervertebral disk. • The uOmnispace.CT Liver Evaluation application is intended to provide processing and visualization for liver segmentation and vessel extraction. It also provides a tool for the user to perform liver separation and residual liver segments evaluation. • The uOmnispace.CT Dual Energy is a post-processing software package that accepts UIH CT images acquired using different tube voltages and/or tube currents of the same anatomical location. The Dual Energy application is intended to provide information on the chemical composition of the scanned body materials and/or contrast agents. Additionally, it enables images to be generated at	• The uOmnispace.CT Dynamic Analysis application is intended to support visualization of the CT datasets over time with the 3D/4D display modes. • The uOmnispace.CT Bone Structure Analysis application is intended to provide visualization and labels for the ribs and spine, and support batch function for intervertebral disk. • The uOmnispace.CT Liver Evaluation application is intended to provide processing and visualization for liver segmentation and vessel extraction. It also provides a tool for the user to perform liver separation and residual liver segments evaluation. • The uOmnispace.CT Dual Energy is a post-processing software package that accepts UIH CT images acquired using different tube voltages and/or tube currents of the same anatomical location. The uOmnispace.CT Dual Energy application is intended to provide information on the chemical composition of the scanned body materials and/or contrast agents. Additionally, it enables images to	

	multiple energies within the available spectrum. • The uOmnispace.CT Cardiovascular Combined Analysis is an image analysis software package for evaluating contrast enhanced CT images. The CT Cardiovascular Combined Analysis is intended to analyze vascular and cardiac structures.It can be used in the qualitative and quantitative for the analysis of head-neck, abdomen, multi-body part combined, TAVR (Transcatheter Aortic Valve Replacement) CT data as input for the planning of cardiovascular procedures. • The uOmnispace.CT Body Perfusion is intended to analyze blood flow information of dynamic CT images, by providing various perfusion-related parameters of the body parts.	be generated at multiple energies within the available spectrum. • The uOmnispace.CT Cardiovascular Combined Analysis is an image analysis software package for evaluating contrast enhanced CT images. The CT Cardiovascular Combined Analysis is intended to analyze vascular and cardiac structures. It can be used in the qualitative and quantitative for the analysis of head-neck, abdomen, multi-body part combined, TAVR (Transcatheter Aortic Valve Replacement) CT data as input for the planning of cardiovascular procedures.	

Application	**Function name**	**Proposed device** uOmnispace.CT	**Predicate Device** uOmnispace.CT (K233209)	**Remark**
Lung Density Analysis	Lung Segmentation	Yes	Yes	Functional Substantially Equivalent (Note 1)
	Lung Density Analysis	Yes	Yes	Same
	Lung Contour Editing	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
	Pulmonary lobes Segmentation	Yes	Yes	Same
	Airway Segmentation	Yes	Yes	Functional Substantially Equivalent (Note 1)
	Airway Tree Extraction and Editing	Yes	Yes	Same
	Airway Contour Editing	Yes	Yes	Same
	Statistical Analysis	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function Name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Brain Perfusion	Motion Correction	Yes	Yes	Same
	Vein and Artery Definition	Yes	Yes	Same
	Parameter Map Calculation	Yes	Yes	Same
	Time-density curve analysis	Yes	Yes	Same
	Tmax	Yes	Yes	Same
	Ischemic penumbra analysis	Yes	Yes	Same
	Symmetric ROI and ROI Template	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Heart	Multi-Phase Loading	Yes	Yes	Same
	Hyper Realistic Rendering	Yes	Yes	Same
	Heart Chamber Segmentation	Yes	Yes	Functional Substantially Equivalent (Note 1)
	Coronary Artery Extraction	Yes	Yes	Functional Substantially Equivalent (Note 1)
	Editing Tools	Yes	Yes	Same
	Centerline Extraction	Yes	Yes	Same
	Stenosis Analysis	Yes	Yes	Same
	Plaque Analysis	Yes	Yes	Same
	Cardiac function Assessment	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Calcium Scoring	Calcium sites segmentation	Yes	Yes	Same
	Calculate Calcium score	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Bone Structure Analysis	Labeling Ribs	Yes	Yes	Same
	Labeling Spine	Yes	Yes	Same
	Batch	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Dynamic Analysis	Motion correction	Yes	Yes	Same
	Multiple phase viewing	Yes	Yes	Same
	Bone Removal	Yes	Yes	Same
	Data Loading and 3D/4D Display	Yes	Yes	Same
	Artery and Vein Display	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Liver Evaluation	Phase Selection	Yes	Yes	Same
	Liver Segmentation	Yes	Yes	Functional Substantially Equivalent (Note 1)
	Lesion Segmentation	Yes	Yes	Same
	Rib Segmentation and manual correction	Yes	Yes	Same
	Vessel Extraction	Yes	Yes	Functional Substantially Equivalent (Note 1)
	Vascular Editing	Yes	Yes	Same
	Liver Segments	Yes	Yes	Same
	Virtual Planning	Yes	Yes	Same
	RFA	Yes	Yes	Same
	Vascular Territories Computation and visualization	Yes	Yes	Same
	Measurement	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Dual Energy	Mono Energetic Image	Yes	Yes	Same
	Mixed Enhanced Image	Yes	Yes	Same
	CNR(Contrast Noise Ratio) Image	Yes	Yes	Same
	Base Material Images: Including Water-Iodine, Water-Calcium, Calcium-Iodine, Uric acid-Calcium, Water-HAP, Liver-Fat Base Material Pair image.	Yes	Yes	Same
	Image Registration	Yes	Yes	Same
	Effective Atomic Number Images ● Component analysis of kidney stones, uric acid stones or non-uric acid stones ● Component analysis of joint gout, uric acid gout or non-uric acid gout	Yes	Yes	Same
	Electron Density Images	Yes	Yes	Same
	Virtual Non contrast Images	Yes	Yes	Same
	Save. Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Dental Application	Defining the Reference Plane	Yes	Yes	Same
	Plotting Panoramic Curve	Yes	Yes	Same
	Marking the Nerve Canals	Yes	Yes	Same
	Cross Sectional Operations	Yes	Yes	Same
	Dental VRT Display	Yes	Yes	Same
	Save, Report, Print(True size printing)	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Colon Analysis	Colon Segmentation and Centerline Calculate	Yes	Yes	Same
	Electronic Colon Cleansing	Yes	Yes	Same
	Manual Polyps Marking	Yes	Yes	Same
	Colon editing and Center Line editing	Yes	Yes	Same
	Polyps' Quantitative Calculation and Analysis	Yes	Yes	Same
	Virtual Endoscopy	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Vessel Analysis	Bone removal	Yes	Yes	Functional Substantially Equivalent (Note 1)
	Vessel and centerlines Extraction	Yes	Yes	Same
	Semi-automatic vessel extraction	Yes	Yes	Same
	Vascular Measurement and vascular stenosis analysis	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same
	Hyper Realistic Rendering	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate Device uOmnispace.CT (K233209)	Remark
Lung Nodule	Marking Nodules	Yes	Yes	Same
	Follow-up Analysis	Yes	Yes	Same
	Lung Segmentation	Yes	Yes	Same
	Nodule Segmentation	Yes	Yes	Same
	Measurement for the segmented nodule	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	**Function name**	**Proposed device** uOmnispace.CT	**Predicate Device** uOmnispace.CT (K233209)	**Remark**
Cardiovascular Combined Analysis	Vessel analysis: ● Bone removal ● Vessel and centerlines Extraction ● Semi-automatic vessel extraction ● Vascular Measurement and vascular - stenosis analysis ● Hyper Realistic Rendering	Yes	Yes	Functional Substantially Equivalent (Note 1)
	Heart Analysis: ● Multi-Phase Loading ● Hyper Realistic Rendering ● Heart Chamber Segmentation ● Coronary Artery Extraction ● Editing Tools ● Centerline Extraction ● Stenosis Analysis ● Plaque Analysis ● Cardiac function Assessment	Yes	Yes	Functional Substantially Equivalent (Note 1)
	Fusion Review: ● The Combined Display of Heart and Vessels tissue	Yes	Yes	Same
	TAVR Evaluation: ● Automatic Aortic annulus location and manually correction ● Automatic Coronary ostia Location and manually correction ● Multi-parameter Calculation	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	**Function Name**	**Proposed device** uOmnispace.CT	**Predicate Device** uOmnispace.CT (K233209)	**Reference Device** CT Perfusion 4D (K193289)	**Remark**
Body Perfusion	Motion Correction	Yes	Yes	/	Functional Substantially Equivalent（Note 2）
	Segmentation	Yes	Yes	/	Functional Substantially Equivalent（Note 3）
	Vessel Definition	Yes	/	Yes	Functional Substantially Equivalent（Note 4）
	Parameter Map Calculation	Yes	/	Yes	Functional Substantially Equivalent（Note 4）
	ROI Tools	Yes	Yes	/	Functional Substantially Equivalent（Note 5）
	Time-density curve analysis	Yes	Yes	/	Functional Substantially Equivalent（Note 5）
	Save, Report, Print	Yes	Yes	/	Same

Note 1

Compared to predicate device, the proposed device introduces deep-learning algorithm. This algorithm supports the substantively equivalent functions as uOmnispace.CT (K233209). This difference between the proposed device and the predicate device doesn't impact the safety and effectiveness of the proposed device.

Note 2

Compared to predicate device, the proposed device integrates both rigid and non-rigid motion correction algorithms, which is substantively equivalent as those in Brain Perfusion and Liver Evaluation in uOmnispace.CT (K233209). This difference between the proposed device and the predicate device doesn't impact the safety and effectiveness of the proposed device.

Note 3

Compared to predicate device, the proposed device integrates both HU segmentation and auto liver segmentation algorithms, which is substantively equivalent as those in Brain Perfusion and Liver Evaluation in uOmnispace.CT (K233209). This difference between the proposed device and the predicate device doesn't impact the safety and effectiveness of the proposed device.

Note 4

Compared to predicate device, the proposed device is substantively equivalent to the predicate device CT Perfusion 4D (K193289). This difference between the proposed device and the predicate device and reference device doesn’t impact the safety and effectiveness of the proposed device.

Note 5

Compared to predicate device, the proposed device supports the substantively equivalent function as Brain Perfusion in uOmnispace.CT (K233209). This difference between the proposed device and the predicate device and reference device doesn’t impact 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
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
These algorithms based on ML/AI method:

- ✓ Lung density Analysis - Lung segmentation algorithm
- ✓ Lung density Analysis - Airway segmentation algorithm
- ✓ Vessel Analysis - Automatic bone removal (Abdomen & Limbs) algorithm
- ✓ Vessel Analysis - Automatic bone removal (Head & Neck) algorithm
- ✓ Heart - Coronary artery extraction algorithm
- ✓ Heart - Heart chamber segmentation algorithm
- ✓ Liver Evaluation - Liver segmentation algorithm
- ✓ Liver Evaluation - Hepatic artery segmentation algorithm

- ✓ Liver Evaluation - Portal vein segmentation algorithm
- ✓ Liver Evaluation - Hepatic vein segmentation algorithm

To validate the uOmnispace.CT applications from a clinical perspective, the deep learning-based algorithm contained in the product underwent a scientific evaluation. More information about the testing on ML/AI algorithm is as follows:

1. Lung density Analysis:

The performance testing for the AI-based lung segmentation algorithm and airway segmentation algorithm was performed on 100 subjects during product development.

- **Acceptance Criteria**

In order to verify the effectiveness of the algorithm in the proposed device, we compared the segmentation results with the ground truth. The validation type and acceptance criteria is shown below：

Validation Type	Algorithm	Acceptance Criteria
Dice	Lung segmentation	0.97
Dice	Airway segmentation	0.86

- **Testing Data Information**

The test dataset comprises 100 cases of Chest CT scans, which covered different gender, age (ages ranging from 1 month to 91 years old) and anatomical variants. The information of distribution was as follows:

Subgroup	Distribution	Quantity
Sex	F	38
	M	62
Age	[0.1,12)	36
	[12,22)	14
	[22,60)	22
	>=60	25
	Unknown	3
Anatomical variation	With anatomical variation	56
	Without anatomical variation	44

- **Performance Testing Summary**

The results output by algorithm were compared with the reference standard, the value of Dice coefficient was shown in the table below, which is higher than the acceptance criteria:

Algorithm	Global performance (Dice Similarity Coefficient)
lung segmentation	0.9801
airway segmentation	0.8954

The subgroup analysis was conducted based on gender, age and anatomical variants. The results were shown in the table below, demonstrating that the algorithms have good generality across different subgroups:

Subgroup	Distribution	Lung segmentation	Airway segmentation
Sex	F	0.9792	0.8957
	M	0.9806	0.8951
Age	[0.1,12)	0.9792	0.8875
	[12,22)	0.9805	0.8929
	[22,60)	0.9813	0.907
	>=60	0.9803	0.9023
	Unknown	0.9779	0.9028
Anatomical variation	With anatomical variation	0.9797	0.8931
	Without anatomical variation	0.9799	0.8957

- **Standard Annotation Process**

For ground truth annotations, all ground truth are annotated by well-trained annotators. Finally, a senior clinical specialist will check and modify annotations to make sure the ground truth is correct.

- **Testing & Training Data Independence**

The training data used for the training of the Lung segmentation algorithm is independent of the data used to test the algorithm.

2. Vessel Analysis:

The performance testing for the AI-based bone removal algorithm was performed on 156 data subjects during product development.

- **Acceptance Criteria**

In order to verify the effectiveness of the algorithm in the proposed device, we compared the segmentation results with the ground truth. The validation type and acceptance criteria is shown below：

Validation Type	Algorithm	Acceptance Criteria
Dice	Bone removal (Abdomen & Limbs)	0.9
Dice	Bone removal (Head & Neck)	0.93

- **Testing Data Information**

The test dataset comprises 156 cases of CTA scans, which covered different gender, age (ages ranging from 13 to 85 years old) and anatomical variants. The information of distribution was as follows:

Subgroup	Distribution	Quantity
Sex	F	54
	M	96
	Unknown	6
Age	[12,22)	46
	[22,60)	41
	>=60	60
	Unknown	9
Anatomical variation	With anatomical variation	28
	Without anatomical variation	128
Body parts	Abdomen & Limbs	98
	Head & Neck	58

- **Performance Testing Summary**

The results output by algorithm were compared with the reference standard, the value of Dice coefficient was shown in the table below, which is higher than the acceptance criteria:

Algorithm	Global performance (Dice Similarity Coefficient)
Bone removal (Abdomen & Limbs)	0.96957
Bone removal (Head & Neck)	0.955

The subgroup analysis was conducted based on gender, age and anatomical variants. The results were shown in the table below, demonstrating that the algorithms have good generality across different subgroups:

Subgroup	Distribution	Bone removal (Abdomen & Limbs)	Bone removal (Head & Neck)
Sex	F	0.9662	0.955
	M	0.9718	0.955
Age	[12,22)	0.9605	0.94
	[22,60)	0.9743	0.956
	>=60	0.9723	0.964
Anatomical variation	With anatomical variation	0.9683	0.966
	Without anatomical variation	0.97	0.958

- **Standard Annotation Process**

For ground truth annotations, all ground truth are annotated by well-trained annotators. Finally, a senior clinical specialist will check and modify annotations to make sure the ground truth is correct.

- **Testing & Training Data Independence**

The training data used for the training of the Lung segmentation algorithm is independent of the data used to test the algorithm.

3. Heart:

The performance testing for the AI-based coronary artery extraction algorithm and heart chamber segmentation algorithm was performed on 72 subjects during product development.

- **Acceptance Criteria**

In order to verify the effectiveness of the algorithm in the proposed device, we compared the segmentation results with the ground truth. The validation type and acceptance criteria is shown below：

Validation Type	Algorithm	Acceptance Criteria
Dice	Coronary artery extraction	0.870
Dice	Heart chamber segmentation	0.910

- **Testing Data Information**

The test dataset comprises 72 cases of CCTA scans, which covered different gender, age (ages ranging from 12 to 92 years old) and anatomical variants. The information of distribution was as follows:

Subgroup	Distribution	Quantity
Sex	F	17
	M	49
	Unknown	6
Age	[12,22)	12
	[22,60)	10
	>=60	35
	Unknown	15
Anatomical variation	With anatomical variation	53
	Without anatomical variation	7
	Unknown	12

- **Performance Testing Summary**

The results output by algorithm were compared with the reference standard, the value of Dice coefficient was shown in the table below, which is higher than the acceptance criteria:

Algorithm	Global performance (Dice Similarity Coefficient)
Coronary artery extraction	0.916
Heart chamber segmentation	0.970

The subgroup analysis was conducted based on gender, age and anatomical variants. The results were shown in the table below, demonstrating that the algorithms have good generality across different subgroups:

Subgroup	Distribution	Coronary artery extraction	Heart chamber segmentation
Sex	F	0.915	0.969
	M	0.918	0.971
	Unknown	0.912	0.963
Age	[12,22)	0.908	0.962
	[22,60)	0.926	0.974
	>=60	0.915	0.971
	Unknown	0.920	0.971
Anatomical variation	With anatomical variation	0.915	0.970

	Without anatomical variation	0.924	0.971
	Unknown	0.908	0.962

- **Standard Annotation Process**

For ground truth annotations, all ground truth are annotated by well-trained annotators. Finally, a senior clinical specialist will check and modify annotations to make sure the ground truth is correct.

- **Testing & Training Data Independence**

The training data used for the training of the Lung segmentation algorithm is independent of the data used to test the algorithm.

4. Liver Evaluation:

The performance testing for the AI-based liver segmentation algorithm and hepatic artery segmentation algorithm were performed on 74 subjects during product development.
The performance testing for the AI-based hepatic portal vein segmentation algorithm and hepatic vein segmentation algorithm were performed on 80 subjects during product development.

- **Acceptance Criteria**

In order to verify the effectiveness of the algorithm in the proposed device, we compared the segmentation results with the ground truth. The validation type and acceptance criteria is shown below：

Validation Type	Algorithm	Acceptance Criteria
Dice	Liver segmentation	0.97
Dice	Hepatic artery segmentation	0.85
Dice	Hepatic portal vein segmentation	0.89
Dice	Hepatic vein segmentation	0.86

- **Testing Data Information**

The test dataset of liver segmentation algorithm and hepatic artery segmentation algorithm, comprises 74 cases of Chest CT scans, which covered different gender, age (ages ranging from 12 to 100 years old) and anatomical variants. The information of distribution was as follows:

Subgroup	Distribution	Quantity
Sex	F	17
	M	34
	unknown	23
Age	[12,22)	14
	[22,60)	23
	>=60	14
	unknown	23
Anatomical variation	With anatomical variation	50
	Without anatomical variation	24

The test dataset of hepatic portal vein segmentation algorithm and hepatic vein segmentation algorithm, comprises 80 cases of Chest CT scans, which covered different gender, age (ages ranging from 12 to 80 years old) and anatomical variants. The information of distribution was as follows:

Subgroup	Distribution	Quantity
Sex	F	25
	M	25
	unknown	30
Age	[12,22)	12
	[22,60)	21
	>=60	20
	unknown	30
Anatomical variation	With anatomical variation	51
	Without anatomical variation	29

- **Performance Testing Summary**

The results output by algorithm were compared with the reference standard, the value of Dice coefficient was shown in the table below, which is higher than the acceptance criteria:

Algorithm	Global performance (Dice Similarity Coefficient)
Liver segmentation	0.981
Hepatic artery segmentation	0.927

Hepatic portal vein segmentation	0.933
Hepatic vein segmentation	0.914

The subgroup analysis was conducted based on gender, age and anatomical variants. The results were shown in the table below, demonstrating that the algorithms have good generality across different subgroups:

Subgroup	**Distribution**	**Liver segmentation**	**Hepatic artery segmentation**	**Hepatic portal vein segmentation**	**Hepatic vein segmentation**
Sex	F	0.981	0.928	0.932	0.924
	M	0.98	0.926	0.93	0.918
	unknown	0.981	0.926	0.936	0.91
Age	[12,22)	0.978	0.921	0.925	0.906
	[22,60)	0.982	0.93	0.934	0.929
	>=60	0.98	0.926	0.933	0.928
	unknown	0.981	0.926	0.936	0.91
Anatomical variation	With anatomical variation	0.981	0.927	0.933	0.915
	Without anatomical variation	0.98	0.925	0.932	0.919

- **Standard Annotation Process**

For ground truth annotations, all ground truth are annotated by well-trained annotators. Finally, a senior clinical specialist will check and modify annotations to make sure the ground truth is correct.

- **Testing & Training Data Independence**

The training data used for the training of the Lung 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 (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).

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above; the uOmnispace.CT 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 device.