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

May 17, 2024

Re: K233209
Trade/Device Name: 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 12, 2024
Received: April 12, 2024

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.

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, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233209

Device Name
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 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 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 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.

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 K233209

1. Date of Preparation:

May 16, 2024

2. Sponsor Identification

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

Establishment Registration Number: 3011015597

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3. Identification of Proposed Device

Trade Name: uOmnispace.CT
Common Name: Medical image management and processing system
Model: 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: K183170
Common Name: Medical image management and processing system
Model: uWS-CT

Regulatory Information

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

Reference Device#1
510(k) Number: K230162
Device Name: uCT 760 with uWS-CT-Dual Energy Analysis, uCT 780 with uWS-CT-Dual Energy Analysis

Reference Device#2
510(k) Number: K230039
Device Name: uOmnispace

Reference Device#3
510(k) Number: K170221
Device Name: syngo.CT Cardiac Planning

Reference Device#4
510(k) Number: K133643
Device Name: syngo.CT Liver Analysis

Reference Device#5
510(k) Number: K182130
Device Name: iSchema View's RAPID

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

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 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 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.

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 uWS-CT(K183170)	Remark
General			
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 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	uWS-CT 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 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 CT Dental application is intended to provide the user a tool to reconstruct panoramic and paraxial views of jaw. • The CT Lung Density application is intended to provide the user a number of density parameters and structure information for evaluating tomogram scans of the lung. • The 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 CT Vessel Analysis application is intended to provide a tool for viewing, manipulating, and evaluating CT vascular images. • The CT Brain Perfusion application is intended to calculate the parameters such as: CBV, CBF, etc. in order to analyze functional blood flow	Substantial Equivalence. The proposed device includes more applications, which are discussed in the following sections, than the predicate device. This difference will not impact the safety and effectiveness of the device.

Item	Proposed Device uOmnispace.CT	Predicate Device uWS-CT(K183170)	Remark
	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 Analysis 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	information about a region of interest (ROI) in the brain. • The CT Heart application is intended to segment heart and extract coronary artery. It also provides analysis of vascular stenosis, plaque and heart function. • The CT Calcium Scoring application is intended to identify calcifications and calculate the calcium score. • The CT Dynamic Analysis application is intended to support visualization of the CT datasets over time with the 3D/4D display modes. • The 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 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.	

Item	Proposed Device uOmnispace.CT	Predicate Device uWS-CT(K183170)	Remark
	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.		

Application	**Function name**	**Proposed device** uOmnispace.CT	**Predicate device:** uWS-CT(K183170)	**Remark**
uOmnispace.CT Lung Density Analysis	Lung Segmentation	Yes	Yes	Same
	Lung Density Analysis	Yes	Yes	Same
	Lung Contour Editing	Yes	Yes	Same
	Pulmonary lobes Segmentation	Yes	Yes	Same
	Airway Segmentation	Yes	Yes	Same
	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 uOmnisapce.CT	Predicate Device: uWS-CT (K183170)	Reference Device#5 iSchema View's RAPID （K182130）	Remark
uOmnispace.CT Brain Perfusion	Motion Correction	Yes	Yes	/	Same
	Arterial Detection	Yes	Yes	/	Same
	Parameter Map Calculation	Yes	Yes	/	Same
	Time-density curve analysis	Yes	Yes	/	Same
	Tmax	Yes	/	Yes	Functional Substantial Equivalent Note 1
	Ischemic penumbra analysis	Yes	/	Yes	Functional Substantial Equivalent Note 2
	Symmetric ROI and ROI Template	Yes	Yes	/	Same
	Save, Report, Print	Yes	Yes	/	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate device: uWS-CT (K183170)	Reference device#2 UOmnispace (K230039)	Remark
uOmnispace. CT Heart	Multi-Phase Loading	Yes	Yes	/	Same
	Hyper Realistic Rendering	Yes	/	Yes	Same
	Heart Chamber Segmentation	Yes	Yes	/	Same
	Coronary Artery Extraction	Yes	Yes	/	Same
	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	/	Functional Substantial Equivalent Note 3
	Save, Report, Print	Yes	Yes	/	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate device: uWS-CT(K183170)	Remark
uOmnispace.CT Calcium Scoring	Calcium sites segmentation	Yes	Yes	Same
	Calculate Calcium score	Yes	Yes	Functional Substantially Equivalent Note 4
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate device: uWS-CT(K183170)	Remark
uOmnispace.CT Bone Structure Analysis	Labeling Ribs	Yes	Yes	Functional Substantial Equivalent Note 5
	Labeling Spine	Yes	Yes	Functional Substantial Equivalent Note 6
	Batch	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uOmnispace.CT	Predicate device: uWS-CT (K183170)	Remark
uOmnispace.CT 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 uWS-CT (K183170)	Reference device#3 uOmnispace (K230039)	Reference device#4 syngo.CT Liver Analysis (K133643)	Remark
uOmnispace.CT Liver Evaluation	Phase Selection	Yes	Yes	/	/	Same
	Liver Segmentation	Yes	Yes	/	/	Same
	Lesion Segmentation	Yes	Yes	/	/	Same
	Rib Segmentation and manual correction	Yes	/	Yes	/	Same
	Vessel Extraction	Yes	Yes	/	/	Same
	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	Functional Substantial Equivalent Note 7
	Measurement	Yes	Yes	/	/	Same
	Save, Report, Print	Yes	Yes	/	/	Same

Application	Function name	Proposed device uOmnispace.CT	Reference Device#1: uCT 760 with uWS-CT-Dual Energy Analysis, uCT 780 with uWS-CT-Dual Energy Analysis（K230162）	Remark
uOmnispace.CT 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	Functional Substantially Equivalent Note 8
	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	Functional Substantial Equivalent Note 9
	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: uWS-CT(K183170)	Remark
uOmnispace.CT 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	Functional Substantial Equivalent Note 10

Application	Function name	Proposed device uOmnispace.CT	Predicate device: uWS-CT(K183170)	Remark
uOmnispace.CT 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: uWS-CT(K183170)	Reference device#3 uOmnispace (K230039)	Remark
uOmnispace.CT Vessel Analysis	Bone removal	Yes	Yes	/	Same
	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: uWS-CT(K183170)	Remark
uOmnispace.CT 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: uWS-CT (K183170)	Reference device#3 Syngo.via (K170221)	Remark
uOmnispace.CT 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 Substantial Equivalent Note 11.
	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 Substantial Equivalent Note 12.
	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	Functional Substantial Equivalent Note 13
	Save, Report, Print	Yes	Yes	/	Same

Note 1:
Compared to reference device, the parameter principle and the functional implementation mode of Tmax is consistent with RAPID. Additional verification tests were carried out to demonstrate that uOmnispace.CT yields accurate quantitative perfusion parameters. Therefore, this technological difference does not raise new issues of safety and effectiveness as compared to RAPID.

Note 2:
Compared to reference device, the function implementse of Ischemic Penumbra Analysis is consistent with RAPID. Additional verification tests were carried out to demonstrate that uOmnispace.CT yields accurate quantitative perfusion parameters. Therefore, this technological difference does not raise new issues of safety and effectiveness as compared to RAPID.

Note 3:
Compared to predicate device, the proposed device add the calculation of parameters related to the left and right atria. These calculation is similar to the calculation of registered ventricular parameters. 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 adds the comparison of the computed Agatston Score to cited literature called Distribution of Coronary Artery Calcium by Race, Gender, and Age. The added function supports to compare the CAC between the current patient and the normal people based on MESA database. The operating principle and the scientific technology are the same, this difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the proposed device.

Note 5:
Compared to predicate device, the proposed device optimizes a new algorithm based on deep learning. This algorithm supports the same function as uWS-CT (K183170). This difference between the proposed device and the predicate device doesn't impact the safety and effectiveness of the proposed device.

Note 6:
Compared to predicate device, the proposed device optimizes a new algorithm based on deep learning. This algorithm supports the same function as uWS-CT (K183170). This difference between the proposed device and the predicate device doesn't impact the safety and effectiveness of the proposed device.

Note 7:
Compared to predicate device, the proposed device support territories computation and visualization based on vessel branches. The operating principle and the scientific technology are the same. There would be no clinically significant difference in the safety and clinical performance of the proposed device.

Note 8:
Compared to predicate device, the proposed device supports the generation of more base material pairs. There is no change in algorithm and this algorithm support the same function as K230162. This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the proposed device.

Note 9:
Compared to predicate device, the proposed device increased the volume calculation based on the effective Atomic Number Image, the volume calculation is the process of pixel counting. There is no change in algorithm and this algorithm support the same function as K230162. This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the proposed device.

Note 10:
Compared to predicate device, the proposed device adds true size printing, there is no change in operating principle and it is only through the ratio of the printed image scale to the real physical scale. Therefore, the real size of the print effect is obtained. This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the proposed device.

Note 11:
For uOmnispace.CT Cardiovascular Combined Analysis application, it integrates uOmnispace.CT Vessel Analysis application and uOmnispace.CT Heart application, these two applications are the same as the CT Vessel Analysis application and the CT Heart application in K183170. There would be no impact on safety and effectiveness of this function.

Note 12:
The function of cardiac analysis refer to uOmnispace.CT Heart.
For uOmnispace.CT Cardiovascular Combined Analysis application, it integrates uOmnispace.CT Vessel Analysis application and uOmnispace.CT Heart application, these two applications are the same as the CT Vessel Analysis application and the CT Heart application in K183170. There would be no impact on safety and effectiveness of this function.

Note 13:
For uOmnispace.CT Cardiovascular Combined Analysis application, TAVR Evaluation is substantively equivalent to the predicate device Syngo.via (K170221). Additionally, the proposed device can provide the length of left and right coronary ostium to annulus. Testing was performed to ensure the measurements meet the predetermined acceptance values. This difference between the proposed device and the 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 Verification and Validation
Software verification and validation testing was provided to demonstrate the Basic Documentation Level, including:

- 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
There are three algorithms based on ML/AI method:

- ✓ Spine labeling algorithm
- ✓ Rib labeling algorithm
- ✓ TAVR analysis algorithm

More information about the ML/AI algorithm is as follows:

1. Spine labeling Algorithm
The performance testing for deep learning-based spine labeling algorithm was performed on 120 subjects (data shown in Table 8-2) during the product development.

- **Acceptance Criteria**

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

Table 8-1. Validation type and acceptance criteria

Validation Type	Acceptance Criteria
Score based on ground truth	The average score of the proposed device results is higher than 4 points.

- **Testing Data Information**

1) Equipment and Protocols

CT data were acquired from five major manufacturers (GE, Phillips, Siemens, Toshiba, UIH), and with tube voltage of 80 - 140kVp, slice thickness of 0.625-3.75 mm.

2) Clinical Subgroup Information

The subgroup information of testing data is summarized below.

Table 8-2. Testing data subgroup information

Subgroup	Details of Each Subgroup	Sample Size
Ethnicity	U.S.	90
	Asia	30
Age	[22, 25]	4
	[26, 40]	11
	[41, 60]	25
	[61, 75]	52
	[76, 100]	9
	Unknown	18
Gender	Female	50
	Male	63
	Unknown	7
BMI (kg/m(2))	< 18.5	6
	[18.5, 25)	19
	>=25	37
	Unknown	58

- **Performance Testing Summary**

The average score of the proposed device results to be validated is 5 points, which is greater than 4 points. Meanwhile, the subgroup analysis shows that (Table 8-3) the proposed device algorithm has good generalization in different subgroups.

Table 8-3. Subgroup performance test

Ethnicity	Average Score of All Test Dataset
U.S.	5.0
Asia	5.0
Age	**Average Score of All Test Dataset**
[22, 25]	5.0
[26, 40]	5.0
[41, 60]	5.0
[61, 75]	5.0
[76, 100]	5.0
Unknown	5.0
Gender	**Average Score of All Test Dataset**
Female	5.0
Male	5.0
Unknown	5.0

BMI (kg/m(2))	Average Score of All Test Dataset
< 18.5	5.0
[18.5, 25)	5.0
>=25	5.0
Unknown	5.0

- **Standard Annotation Process**

For ground truth annotations, all ground truth are annotated by well-trained annotators.

The annotators use an interactive tool to observe the image, and then set annotation points near the center of vertebral body and assign anatomical labels. Finally, all ground truth are evaluated by two licensed physicians with U.S. credentials.

- **Testing & Training Data Independence**

The training data used for the training of the spine labeling algorithm is independent of the data used to test the algorithm.

2. Rib labeling Algorithm

The performance testing for deep learning-based rib labeling algorithm was performed on 120 subjects (data shown in Table 8-5) during the product development.

- **Acceptance Criteria**

The validation type and acceptance criteria is shown in the Table 8-4 below:

Table 8-4. Validation type and acceptance criteria

Validation Type	Acceptance Criteria
Score based on ground truth	The average score of the proposed device results is higher than 4 points.

- **Testing Data Information**

1) Equipment and Protocols

CT data were acquired from five major manufacturers (GE, Phillips, Siemens, Toshiba, UIH), and with tube voltage of 80 - 140kVp, slice thickness of 0.625-3.75 mm.

2) Clinical Subgroup Information

The subgroup information of testing data is summarized below.

Table 8-5. Testing data subgroup information

Subgroup	Details of each subgroup	Sample Size
Ethnicity	U.S.	80
	Asia	40
Age	[22, 25]	4
	[26, 40]	14
	[41, 60]	25
	[61, 75]	46
	[76, 100]	18
	Unknown	13

Gender	Female	54
	Male	66
BMI (kg/m(2))	< 18.5	10
	[18.5, 25)	23
	>=25	36
	Unknown	51

- **Performance Testing Summary**

The average score of the proposed device results to be validated is 5 points, which is greater than 4 points. Meanwhile, the subgroup analysis shows that (Table 8-6) the proposed device algorithm has good generalization in different subgroups.

Table 8-6. Subgroup performance test

Ethnicity	**Average Score of All Test Dataset**
U.S.	5.0
Asia	5.0
Age	**Average Score of All Test Dataset**
[22, 25]	5.0
[26, 40]	5.0
[41, 60]	5.0
[61, 75]	5.0
[76, 100]	5.0
Unknown	5.0
Gender	**Average Score of All Test Dataset**
Female	5.0
Male	5.0
BMI (kg/m(2))	**Average Score of All Test Dataset**
< 18.5	5.0
[18.5, 25)	5.0
>=25	5.0
Unknown	5.0

- **Standard Annotation Process**

For ground truth annotations, all ground truth are annotated by well-trained annotators. A threshold based interactive tool is used to generate initial rib mask, then annotators will refine the rib mask and assign anatomical labels. After the first round annotation, they will check each other's annotation. Finally, all ground truth are evaluated by two licensed physicians with U.S. credentials.

- **Testing & Training Data Independence**

The training data used for the training of the rib labeling algorithm is independent of the data used to test the algorithm.

3. TAVR analysis algorithm

The performance testing for the AI-based TAVR analysis algorithm was performed on 60 subjects (data shown in Table 8-8) during the product development.

- **Acceptance Criteria**

The validation type and acceptance criteria are shown in Table 8-7 below:

Table 8-7. Validation type and acceptance criteria

Validation Type	**Acceptance Criteria**
Verify the consistency with ground truth	The mean landmark error between the proposed device results and ground truth is less than the threshold, 1 mm.
Subjective Scoring of doctors with U.S. professional qualifications	The average score of the evaluation criteria is higher than 2.

- **Testing Data Information**

Table 8-8. Testing data information

Information of data	**Details of each subgroup**	**Sample size**
Sex	Male	29
	Female	21
	Unknown	10
Age	[40, 60)	9
	[60, 70)	16
	[70, 80)	14
	[80, 100)	11
	Unknown	10
Ethnicity	Asia	25
	U.S.	35
US. Facility	U.S. Facility 1	25
	U.S. Facility 2	10

- **Performance Testing Summary:**

The Mean Landmark Error for all data is 0.86 mm, which is less than 1mm. The average scores of two MD with the American Board of Radiology Qualification on the testing data set is 3, which is higher than 2. Meanwhile, the subgroup analysis shows that (Table 8-9) the performance of the algorithm consists of different subgroups.

Table 8-9. Subgroup performance test

All	**Mean Landmark Error (mm)**	**Average Score**
All data	0.86	3
Age	**Mean Landmark Error (mm)**	**Average Score**
[40, 60)	0.888	3
[60, 70)	0.818	3
[70, 80)	0.907	3
[80, 100)	0.845	3
unknown	0.85	3
Gender	**Mean Landmark Error (mm)**	**Average Score**
Female	0.9	3
Male	0.834	3
Unknown	0.85	3
Ethnicity	**Mean Landmark Error (mm)**	**Average Score**
Asia	0.852	3
U.S.	0.866	3
US. Facility	**Mean Landmark Error (mm)**	**Average Score**
U.S. Facility 1	0.872	3

U.S. Facility 2	0.85	3

- **Standard Annotation Process**

For ground truth annotations, all ground truth are annotated by well-trained annotators. After the first round of annotation, they will check each other's annotation. Finally, all ground truth are evaluated by two licensed physicians with U.S. credentials.

- **Testing & Training Data Independence**

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

Other Standards and Guidance

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

Summary

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