December 20, 2023

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

Re: K233176
Trade/Device Name: uOmnispace.MI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 26, 2023
Received: September 28, 2023

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,

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)*

k233176

Device Name

uOmnispace.MI

Indications for Use *(Describe)*

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

■ uOmnispace.MI MM Fusion application is intended to provide tools for viewing, analyzing and reporting PET, CT, MR, SPECT data with its flexible workflow and optimized layout protocols for dedicated reporting purposes on oncology, neurology, cardiology.

■ uOmnispace.MI MM Oncology application is intended to provide tools to display and analyze the follow-up PET, CT, MR data, with which users can do image registration, lesion segmentation, and statistical analysis.

■ uOmnispace.MI Dynamic Analysis application is intended to display PET data and anatomical data such as CT or MR, and supports to do lesion segmentation and output associated time activity curve.

■ uOmnispace.MI NeuroQ application is intended to analyze the brain PET scan, give quantitative results of the relative activity of different brain regions, and make comparison of activity of normal brain regions in AC database or between two studies from the same patient, as well as provide analysis of amyloid uptake levels in the brain.

■ uOmnispace.MI Emory Cardiac Toolbox application is intended to provide cardiac short axis reconstruction, browsing function. And it also performs perfusion analysis, activity analysis and cardiac function analysis of the cardiac short axis.

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

K233176

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.MI

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

4. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K192630
Device Name: uWS-MI

Reference Device#1
510(k) Number: K173897

Device Name: syngo.via MI Workflows

Reference Device#2
510(k) Number: K183170
Device Name: uWS-CT

5. Device Description

The uOmnispace.MI is a post-processing software based on the uOmnispace platform (cleared in K230039) for viewing, manipulating, evaluating and analyzing PET, CT, MR, SPECT images, can run alone or with other advanced commercially cleared applications.

This proposed device contains the following applications:

- uOmnispace.MI MM Fusion
- uOmnispace.MI MM Oncology
- uOmnispace.MI Dynamic Analysis

Additionally, uOmnispace.MI offers the users the options to run the following third-party applications in uOmnispace.MI:

- uOmnispace.MI NeuroQ
- uOmnispace.MI Emory Cardiac Toolbox

6. Indications for use

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

- uOmnispace.MI MM Fusion is intended to provide tools for viewing, analyzing and reporting PET, CT, MR, SPECT data with its flexible workflow and optimized layout protocols for dedicated reporting purposes on oncology, neurology, and cardiology.
- uOmnispace.MI MM Oncology application is intended to provide tools to display and analyze the follow-up PET, CT, and MR data, with which users can do image registration, lesion segmentation, and statistical analysis.
- uOmnispace.MI Dynamic Analysis application is intended to display PET data and anatomical data such as CT or MR, and supports to do lesion segmentation and output associated time activity curve.
- uOmnispace.MI NeuroQ application is intended to analyze the brain PET scan, give quantitative results of the relative activity of different brain regions, and make comparison of activity of normal brain regions in AC database or between two studies from the same patient, as well as provide analysis of amyloid uptake levels in the brain.

- uOmnispace.MI Emory Cardiac Toolbox application is intended to provide cardiac short axis reconstruction, browsing function. And it also performs perfusion analysis, activity analysis and cardiac function analysis of the cardiac short axis.

7. Summary of Technological Characteristics

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

The following tables compare the features, principles of operation, fundamental scientific technology and intended use of uOmnispace.MI when compared to the predicate devices.

Table 1 Substantial equivalent discussion for basic functions

Item	**Proposed Device** uOmnispace.MI	**Predicate Device** uWS-MI (K192630)	**Remark**
General			
Device Classification Name	Medical image management and processing system	Medical image management and processing system	Same
Product Code	LLZ	LLZ	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.MI is a software solution intended to be used for viewing, processing, evaluating and analyzing of PET, CT, MR, SPECT images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications: uOmnispace.MI MM Fusion application is intended to provide tools for viewing, analyzing and reporting PET, CT, MR, SPECT data with its flexible workflow and optimized layout protocols for dedicated reporting purposes on oncology, neurology, cardiology. uOmnispace.MI The MM Oncology application is intended to provide tools to display and analyze the	uWS-MI 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 Oncology application is intended to provide tools to display and analyze the follow-up PET/CT data, with which users can do image registration, lesion segmentation, and statistical analysis. The Dynamic Analysis application is intended to display PET data and anatomical data such as CT or MR, and supports to do lesion segmentation	The indication for use of the proposed device is expanded and replenished. The proposed device includes more applications and functions, which are discussed in the following chapters. The difference will not impact the safety and effectiveness of the device.

Item	Proposed Device uOmnispace.MI	Predicate Device uWS-MI (K192630)	Remark
	follow-up PET, CT, MR data, with which users can do image registration, lesion segmentation, and statistical analysis. uOmnispace.MI Dynamic Analysis application is intended to display PET data and anatomical data such as CT or MR, and supports to do lesion segmentation and output associated time activity curve. uOmnispace.MI NeuroQ application is intended to analyze the brain PET scan, give quantitative results of the relative activity of different brain regions, and make comparison of activity of normal brain regions in AC database or between two studies from the same patient, as well as provide analysis of amyloid uptake levels in the brain. uOmnispace.MI Emory Cardiac Toolbox application is intended to provide cardiac short axis reconstruction, browsing function. And it also performs perfusion analysis, activity analysis and cardiac function analysis of the cardiac short axis.	and output associated time-activity curve. NeuroQ application is intended to analyze the brain PET scan, give quantitative results of the relative activity of 240 different brain regions, and make comparison of activity of normal brain regions in AC database or between two studies from the same patient, as well as provide analysis of amyloid uptake levels in the brain. Emory Cardiac Toolbox application is intended to provide cardiac short axis reconstruction, browsing function. And it also performs perfusion analysis, activity analysis and cardiac function analysis of the cardiac short axis.	

Table 2 Substantial equivalent discussion for MM Fusion

Application	Function name	Proposed device uOmnispace.MI	Predicate device	Reference device#2:	Remark

				uWS-MI (K192630)	uWS-CT (K183170)	
MM Fusion	Image Fusion		Yes	Yes	/	Same
	Study Comparison		Yes	Yes	/	Same
	3D Visualization		Yes	Yes	/	Same
	Registration	Manual Registration	Yes	Yes	/	Same
		Dot Registration	Yes	Yes	/	Same
		Auto Registration	Yes	Yes	/	Same
	Default Layout and Customized Layout		Yes	Yes	/	Functional Substantial Equivalent Note1
	Position Correction		Yes	Yes	/	Same
	Lesion Segmentation	Fix threshold segmentation	Yes	Yes	/	Same
		Percentage threshold segmentation	Yes	Yes	/	Same
		Adaptive threshold segmentation	Yes	Yes	/	Same
	CT Liver Segmentation		Yes	/	Yes	Same
	CT Lung Segmentation		Yes	/	Yes	Same
	Rib Labeling		Yes	/	Yes	Functional Substantially Equivalent Note 2
	Spine Labeling		Yes	/	Yes	Functional Substantially Equivalent Note 3
	Save/Film/Report		Yes	Yes	/	Same

Table 3 Substantial equivalent discussion for MM Oncology

Application	**Function name**		**Proposed device** uOmnispace.MI	**Predicate device** uWS-MI (K192630)	**Reference device#2:** uWS-CT (K183170)	**Reference device#3:** syngo.via MI Workflows (K173897)	**Remark**
MM Oncology	Registration	Manual Registration	Yes	Yes	/	/	Same
		Auto Registration	Yes	Yes	/	/	Same
	One-Step Evaluation		Yes	Yes	/	/	Same
	Lesion Segmentation	Fix threshold segmentation	Yes	Yes	/	/	Same
		Percentage threshold segmentation	Yes	Yes	/	/	Same
		Adaptive threshold segmentation	Yes	Yes	/	/	Same
		Lung nodule segmentation	Yes	Yes	/	/	Same
		Liver tumor segmentation	Yes	Yes	/	/	Same
		Lymph node segmentation	Yes	Yes	/	/	Same
	Spread		Yes	Yes	/	/	Same
	CT liver Segmentation		Yes	/	Yes	/	Same
	CT lung Segmentation		Yes	/	Yes	/	Same
	Rib Labeling		Yes	/	Yes	/	Functional Substantial Equivalent. Note 4
	Spine Labeling		Yes	/	Yes	/	Functional Substantial Equivalent.

							Note 5
	Statistical Analysis		Yes	Yes	/	/	Same
	Reference VOI		Yes	Yes	/	/	Same
	Response Assessment	PERCIST	Yes	Yes	/	/	Same
		RECIST1.0	Yes	Yes	/	/	Same
		RECIST1.1	Yes	/	Yes	/	Same
		Deauville Score	Yes	/	/	Yes	Same
	Save		Yes	Yes	/	/	Same

Table 4 Substantial equivalent discussion for Dynamic Analysis

Application	**Function name**		**Proposed device** uOmnispace.MI	**Predicate device** uWS-MI (K192630)	**Remark**
Dynamic Analysis	Automatic cine		Yes	Yes	Same
	ROI Drawing		Yes	Yes	Same
	Data Recombination		Yes	Yes	Same
	Curve Analysis		Yes	Yes	Same
	Table Quantization Statistics		Yes	Yes	Same
	Save		Yes	Yes	Same
	Print (Filming)		Yes	Yes	Same
	Registration	Manual Registration	Yes	Yes	Same
		Dot Registration	Yes	Yes	Same
		Auto Registration	Yes	Yes	Same
	Lesion Segmentation	Fix threshold segmentation	Yes	Yes	Same
		Percentage threshold segmentation	Yes	Yes	Same
		Adaptive threshold segmentation	Yes	Yes	Same

Note 1: Compared to predicate device, the proposed device optimizes image layout that adds more default layout and adjusts the interaction of customized layout. This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the subject device.

Note 2: 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 cleared). This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the subject device.

Note 3: 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 cleared). This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the subject device.

Note 4: 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 cleared). This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the subject 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 cleared). This difference between the proposed device and the reference device doesn't impact the safety and effectiveness of the subject device.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility
Not Applicable to the proposed device, because the device is stand-alone software.

Electrical Safety and Electromagnetic Compatibility (EMC)
Not Applicable to the proposed device, because the device is stand-alone software.

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

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

- **Design of the performance verification test**

The identification rate is a commonly used evaluation metric to evaluate the labelling performance [1-3], which is defined as the ratio of correctly identified vertebrae/rib to the total number of vertebrae/rib.

As for spine labeling, the mean identification rate of the five top-performing algorithms are 83.3% [2]. For rib labeling, the mean identification rate (label-accuracy) of a SOTA algorithm is 91.5% [3]. If the proposed device algorithm can

achieve comparable performance, it is considered that the proposed device algorithm meets the clinical requirements.

We set a 5-point scoring criteria, and the acceptance criteria was that the average score of the proposed device results is higher than 4 points. 4 points is equivalent to the mean identification rate of spine labeling is greater than 92% (>83.3%, correctly labeled vertebrae number ≥23, total vertebrae number=25, 23/25=92%), and the mean identification rate of rib labeling is greater than 91.7%(>91.5% ， correctly labeled rib number ≥22, total rib number=24, 22/24≈91.7%). So, the setting of evaluation criteria in this way can meet clinical requirements.

Moreover, scoring according to the number of incorrect label is a common way to evaluate the labeling algorithm [1]. The number of incorrect label is directly related to the extra workload of the doctor, e.g. manual correction. While the purpose of the labeling algorithm is to improve the work efficiency of doctors, a more intuitive way is to score according to the number of errors in automatic label

To validate the uOmnispace.MI software from a clinical perspective, the deep learning-based spine labeling algorithm and rib labeling algorithm contained in the product underwent a scientific evaluation. The validation results for the proposed device demonstrated the good performance, the robustness and good generalization ability among different subgroups.

1. Spine labeling Algorithm

The performance testing for deep learning-based spine labeling algorithm was performed on 286 CT scans (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 gold standard	The average score of the proposed device results is higher than 4 points.

- **Testing Data Information**

1) Equipments and Protocols

CT data were acquired with different multidetector (16, 64, 160, 256, 320-slice) CT scanners from five major manufacturers (GE, Phillips, Siemens, Toshiba, UIH), and with tube voltage of 110 - 140 kVp, tube current of 275-1000mA, slice thickness of 0.625-2.0 mm, in-plane spacing of 0.656 - 1.172 mm.

2) Sample Size

Dataset	Patients Number	Samples Number
Testing Dataset	267	286

(Note: One patient may have multiple samples, because of the differences in scanning protocols, such as slice thickness, in-plane spacing)

3) Clinical Subgroup Information

The testing data information is summarized below.

Table 8-2. Testing data information

Information of data	286 spine CTs
Gender	Male: 68 Female: 55 Unknown: 163
Age	(10, 25]: 4 (25, 40]: 16 (40, 60]: 45 (60, 75]: 47 (75, 100]: 14 Unknown: 160
Ethnicity	Asian(Chinese) data: 106 European data: 160 The United States data: 20

- **Performance Testing Summary**

For testing dataset, the average score of the proposed device results to be validated is 4.951 points and 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

Age	Average score of the proposed device
(10, 25]	5.000
(25, 40]	5.000
(40, 60]	5.000
(60, 75]	5.000
(75, 100]	5.000
Unknown	4.914
Gender	Average score of the proposed device
Female	5.000
Male	5.000
Unknown	4.913
Ethnicity	Average score of the proposed device
Asian(Chinese) data	5.000
European data	4.913
The United States data	5.000

- **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, a senior clinical specialist will check and modify annotations to make sure the ground truth correct.

- **Testing & Training Data Independence**

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

Confounders

There are no confounders exist for the training methodology.

2. Rib labeling Algorithm

The performance testing for deep learning-based rib labeling algorithm was performed on 160 CT scans (data shown in Table 8-6) during the product development.

- **Acceptance Criteria**

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

Table8-4. Validation type and acceptance criteria

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

- **Testing Data Information**

1) Equipments and Protocols

CT data were acquired with different multidetector (16, 64, 160, 256, 320-slice) CT scanners from five major manufacturers (GE, Phillips, Siemens, Toshiba, UIH), and with tube voltage of 100-140 kVp, tube current of 275-1000 mA, slice thickness of 0.625-3.0 mm, in-plane spacing of 0.531-1.955 mm.

2) Sample Size

Table 8-5. Sample size information of testing data

Dataset	Patients Number	Samples Number
Testing Dataset	156	160

(Note: One patient may have multiple samples, because of the differences in scanning protocols, such as slice thickness, in-plane spacing.)

3) Clinical subgroups

The clinical subgroups information of the testing data is summarized below.

Table 8-6. Testing data information

Information of data	160 CTs
Gender	Male: 110 Female: 39

	Unknown: 11
Age	(10, 25]: 2 (25, 40]: 14 (40, 60]: 51 (60, 75]: 69 (75, 100]: 24
Ethnicity	Asian(Chinese) data: 80 The United States data: 80

- **Performance Testing Summary**

For the testing dataset, the average score of the proposed device results to be validated is 5 points and greater than 4 points. Meanwhile, the subgroup analysis shows that (Table 8-12) the proposed device algorithm has good generalization in different subgroups.

Table 8-7. Subgroup performance test

Age	Average score of the proposed device
(10, 25]	5.00
(25, 40]	5.00
(40, 60]	5.00
(60, 75]	5.00
(75, 100]	5.00
Gender	Average score of the proposed device
Female	5.00
Male	5.00
Unknown	5.00
Ethnicity	Average score of the proposed device
Asian(Chinese) data	5.00
The United States data	5.00

- **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. At last, a senior clinical specialist will check and modify annotations to make sure the ground truth correct.

- **Testing & Training Data Independence**

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

Confounders

There are no confounders exist for the training methodology.

References:

[1]Major, David , et al. "Automated landmarking and labeling of fully and partially scanned spinal columns in CT images." Medical Image Analysis 17.8(2013):1151-1163.
[2]C, Anjany Sekuboyina A B , et al. "VerSe : A Vertebrae Labelling and Segmentation Benchmark for Multi-detector CT Images." Medical Image Analysis (2021).
[3]Jin L, Gu S, Wei D, et al. "RibSeg v2: A Large-scale Benchmark for Rib Labeling and Anatomical Centerline Extraction". IEEE Transactions on Medical Imaging, 2023. DOI: 10.1109/TMI.2023.3313627.

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.MI 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.