Wisdom Technologies., Inc.
℅ Wei Wang
Regulatory Consultant
11 Longstreet
IRVINE, CA 92620

May 7, 2024

Re: K232928
Trade/Device Name: DeepContour (V1.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: April 5, 2024
Received: April 5, 2024

Dear Wei Wang:

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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging
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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)*

K232928

Device Name

DeepContour (V1.0)

Indications for Use *(Describe)*

DeepContour is a deep learning based medical imaging software that allows trained healthcare professionals to use DeepContour as a tool to automatically process CT images. In addition, DeepCoutour is suitable for the following conditions:

1. Creation of contours using deep-learning algorithms , support quantitative analysis, organ HU distribution statistics, transfer contour files to TPS, and create management archives for patients.

2. Analyze the anatomical structure at different anatomical positions.

3. Rigid and elastic registration based on CT.

4. 3D reconstruction, editing and other visual tools based on organ contours

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

The following information is provided as required by 21 CFR 807.92。

1. SUBMITTER

Name: Wisdom Technologies., Inc.

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Contact Person: Wei Wang, Consultant, Regulatory Affairs
Phone: 949-7849283

Date Prepared: August 24, 2023

2. DEVICE

Subject Device Name: DeepContour v1.0
Common/Trade Name: DeepContour
Product Code and Classification: Medical Image Management And Processing System
21 CFR 892.2050 | QKB | Class II

3. PREDICATE DEVICE

Primary: AI-Rad CAI-Rad Companion Organs RT (K221305) Siemens
Reference: Contour ProtégéAI (K223774) MIM Software

4. DEVICE DESCRIPTION

DeepContour is a deep learning based medical imaging software that allows trained healthcare professionals to use DeepContour as a tool to automatically process CT images. DeepContour contouring workflow supports CT input data and produces RTSTRUCT outputs. The organ segmentation can also be combined into templates, which can be customized by different hospitals according to their needs. DeepContour provides an interactive contouring application to edit and review the contours automatically generated by DeepContour.

5. INDICATIONS FOR USE

DeepContour is a deep learning based medical imaging software that allows trained healthcare professionals to use DeepContour as a tool to automatically process CT images. In addition, DeepCoutour is suitable for the following conditions:

1). Creation of contours using deep-learning algorithms , support quantitative analysis, organ HU distribution statistics, transfer contour files to TPS, and create management archives for patients.

2). Analyze the anatomical structure at different anatomical positions.

3). Rigid and elastic registration based on CT.

4). 3D reconstruction, editing and other visual tools based on organ contours

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The primary technological components of DeepContour and its predicate device are to achieve the deep learning based medical imaging software functions that allows trained healthcare professionals to automatically process CT images. Both are software devices that receive inputs related to radiological images; Both generate contours as output that may be used as input for radiation Treatment Planning Systems and interactive contouring applications to review and edit; Both are software devices for prescription use in a professional environment with no patient contact.

There are no known differences in technological characteristics between the subject device and the predicate device that raise any questions of safety or effectiveness. The technological characteristics of the subject device are believed to be substantially equivalent to the predicate device.

Table 1. Substantial Equivalence Comparison

Area of Comparison	**Subject Device-DeepContour**	**Primary-AI-Rad CAI-Rad Companion Organs RT (K221305) Siemens**	**Reference-Contour ProtégéAI(K223774) MIM Software**
Regulation Number/code	21 CFR 892.2050|QKB	22 CFR 892.2050|QKB	21 CFR 892.2050|QKB
Regulation Name	Medical Image Management And Processing System	Medical Image Management And Processing System	Medical Image Management And Processing System

Indications for Use	DeepContour is a deep learning based medical imaging software that allows trained healthcare professionals to use DeepContour as a tool to automatically process CT images. In addition, DeepCoutour is suitable for the following conditions: 1. Creation of contours using deep-learning algorithms , support quantitative analysis, organ HU distribution statistics, transfer contour files to TPS, and create management archives for patients. 2. Analyze the anatomical structure at different anatomical positions. 3. Rigid and elastic registration based on CT. 4. 3D reconstruction, editing and other visual tools based on organ contours	AI-Rad Companion Organs RT is a post-processing software intended to automatically contour DICOM CT imaging data using deep-learning-based algorithms. Contours that are generated by AI-Rad Companion Organs RT may be used as input for clinical workflows including external beam radiation therapy treatment planning. AI-Rad Companion Organs RT must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by AI-Rad Companion Organs RT. The output of AI-Rad Companion Organs RT in the format of RTSTRUCT objects are intended to be used by trained medical professionals. The software is not intended to automatically detect or contour lesions. Only DICOM images of adult patients are considered to be valid input.	Trained medical professionals use Contour ProtégéAI as a tool to assist in the automated processing of digital medical images of modalities CT and MR, as supported by ACR/NEMA DICOM 3.0. In addition, Contour ProtégéAI supports the following indications: • Creation of contours using machine-learning algorithms for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management. • Segmenting anatomical structures across a variety of CT anatomic locations. • And segmenting the prostate, the seminal vesicles, and the urethra within T2-weighted MR images. Appropriate image visualization software must be used to review and, if necessary, edit results automatically generated by Contour ProtégéAI.

Device description	DeepContour is a deep learning based medical imaging software that allows trained healthcare professionals to use DeepContour as a tool to automatically process CT images. DeepContour contouring workflow supports CT input data and produces RTSTRUCT outputs. The organ segmentation can also be combined into templates, which can be customized by different hospitals according to their needs. DeepContour provides an interactive contouring application to edit and review the contours automatically generated by DeepContour.	AI-Rad Companion Organs RT is a post-processing software used to automatically contour DICOM CT imaging data using deep-learning-based algorithms. AI-Rad Companion Organs RT contouring workflow supports CT input data and produces RTSTRUCT outputs. The configuration of the organ database and organ templates defining the organs and structures to be contoured based on the input DICOM data is managed via a configuration interface. Contours that are generated by AI-Rad Companion Organs RT may be used as input for clinical workflows including external beam radiation therapy treatment planning. The output of AI-Rad Companion Organs RT, in the form of RTSTRUCT objects, are intended to be used by trained medical professionals. The output of AI-Rad Companion Organs RT must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by AI-Rad Companion Organs RT application. At a high-level, AI-Rad Companion Organs RT includes the following functionality: 1. Automated contouring of Organs at Risk (OAR) workflow a. Input –DICOM CT b. Output – DICOM	Contour ProtégéAI is an accessory to MIM software that automatically creates contours on medical images through the use of machine-learning algorithms. It is designed for use in the processing of medical images and operates on Windows, Mac, and Linux computer systems. Contour ProtégéAI is deployed on a remote server using the MIMcloud service for data management and transfer; or locally on the workstation or server running MIM software.

		RTSTRUCT 2. Organ Templates configuration (incl. Organ Database) 3. Web-based preview of contouring results to accept or reject the generated contours.	
Algorithm	Deep Learning	Deep Learning	Machine-learning
Segmentation of Organ at Risk in the Anatomic Regions	Head & Neck, Thorax, Abdomen & Pelvis (82 OARs)	Head & Neck, Thorax, Abdomen & Pelvis Head & Neck lymph nodes (108 OAR)	Head & Neck,Prostate, Thorax, Abdomen, Lungs & Liver, MRT structures (spleen, pelvic lymph nodes, descending aorta, bone)
Compatible Modality	CT Images	CT Images	CT & MR
Compatible Scanner Models	No Limitation on scanner model, DICOM compliance required.	No Limitation on scanner model, DICOM compliance required.	No Limitation on scanner model, DICOM compliance required.
Compatible Treatment Planning System	No Limitation on TPS model, DICOM compliance required.	No Limitation on TPS model, DICOM compliance required.	No Limitation on TPS model, DICOM compliance required.
Contraindications	Adult use only	Adult use only	Adult use only
Target Population	DeepContour is designed for use only in adult populations for whom relevant modality scans , including head and neck, thorax, abdomen, and pelvis, are available .	AI-Rad Companion Organs RT is designed for use only in adult populations. AI-Rad Companion Organs RT is designed for any patient for whom relevant modality scans are available. More specifically, the software is validated on previously acquired CT DICOM volumes for radiation therapy treatment planning, including, head and neck, thorax, abdomen, and pelvis.	No public record found

Clinical condition the device is intended to diagnose, treat or manage	Limited to patients previously selected for Radiation Therapy.	Limited to patients previously selected for Radiation Therapy.	Limited to patients previously selected for Radiation Therapy.
Software Architecture	Server-based application supporting Windows and Local deployment on Windows.	AI-Rad Companion (Engine) architecture enabling the deployment of AI Rad Companion Organs RT using Edge and in the Cloud. The UI is provided using a webbased interface.	Server-based application supporting Linux-based OS and Local deployment on Windows or Mac
Deployment Feature	locally deployed or Cloud-based	Edge & Cloud Deployment	Cloud-based or locally deployed
Organ Templates	Creating, editing and deletion of organ templates. Customize predefined structure database with mapping to international nomenclature schemes.	Creating, editing and deletion of organ templates. Customize predefined structure database with mapping to international nomenclature schemes.	No public record found
Automated workflow	DeepContour automatically processes input image data and sends the results as DICOM-RT Structure Sets to a user-configurable target node.	AI-Rad Companion Organs RT automatically processes input image data and sends the results as DICOM-RT Structure Sets to a user-configurable target node.	Automatic contouring working using machine-learning
Contour visualization and editing feature	DeepContour provides basic result preview of automatic segmentation results, and editing feature of the automatic segmented contour.	AI-Rad Companion Organs RT provides basic result preview of automatic segmentation results, and no editing feature of the automatic segmented contour.	No public record found

Segmentation Performance	The target performance was validated using 100 cases.The mean and standard deviation Dice coefficients, along with the lower 95th percentile confidence bound were calculated.	The target performance was validated using 113 cases distributed to two cohorts. Cohort A is clinical routine treatment planning CT and it is split into two sub-cohort and Cohort B is PET-CT data. To objectively evaluate the target performance, the DICE coefficient, the absolute symmetric surface distance (ASSD) and the fail rate was evaluated. The segmentation performance of the subject and reference device were equivalent as well as the overall performance compared to the predicate device.	739 CT Images from 12 clinical sites were used for testing. The mean and standard deviation Dice coefficients, along with the lower 95th percentile confidence bound were calculated.
User Interface – Results Preview (Confirmation)	Basic visualization functionality of original data and generated contours	Basic visualization functionality of original data and generated contours	Basic visualization functionality of original data and generated contours
User Interface Configuration	Configuration UI	Configuration UI	Configuration UI
Automated Workflow to TPS	Results send to Confirmation UI & Optional bypassing of Confirmation UI to TPS	Results send to Confirmation UI & Optional bypassing of Confirmation UI to TPS	Results send to Confirmation UI & Optional bypassing of Confirmation UI to TPS
Human Factors	Design to be used by trained clinicians.	Design to be used by trained clinicians.	Design to be used by trained clinicians.
Patient Contact	None	None	None

7. PERFORMANCE AND NONCLINICAL TESTS

Software verification and validation were conducted, and the process was documented per FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."*

Verification test results demonstrate conformance to applicable requirements and specifications. Testing against the predicate device demonstrates good agreement, proving that tested device can be used as equivalent contouring software for clinical purposes. No animal studies or clinical tests were required for validation of the software.

7.1 Training Datasets

For DeepContour, the deep learning models were trained on a pool of training data that did not include any patients from the same institution as the test subjects. The data was collected from 35 hospitals across China over a period of about 3 years. The data collection time is random, including patients with different ages, races, size, et al. Data collected in a hospital tends to be a collection of consecutive cases. Due to the different time periods applicable to different hospitals, the time for collecting data varies among different hospitals. The specific patient subgroups were not the special consideration when collecting the patients' data.

The training data included 800 CT images (200 for each region of head and neck region, chest region, abdomen region and pelvic region) at various ages, no ethnicities or genders were excluded from training. Within 200 cases collected in each region, 160 cases were used for training and 40 cases were used for validation to establish the auto-segmentation models. The auto-segmentation process includes two steps: first step to distinguish the four different regions (head and neck region, chest region, abdomen region and pelvic region), second step to call the model of this region to realize auto-segmentation. The initial segmentations were then reviewed and corrected by two radiation oncologists for model training, with a third qualified internal staff member available to adjudicate if needed.

Table 2: Training Data Information

# of Datasets	800
Data Origin	35 hospitals across China
Sex	Male:372 Female:428
Age	<50: 289 50-70: 415 >70:70 Unknown:26 (unknown due to data minimization on customer site)
Body Region	Head and neck region: 200 chest region: 200 abdomen region: 200 pelvic region: 200
CT Scanner	Philips: 301 GE: 226 Simens: 128 Unknown:145 (unknown due to data minimization on customer site)

7.2 Verification datasets

The performance of the DeepContour were verified by a total of 203 CT images with 2 datasets:

(1) clinical datasets retrospectively collected from multiple clinical regions across the Peking Union Medical College Hospital (N=100), consisting of four selected parts based on their location, 25 cases for head and neck, 25 cases for chest, 25 cases for abdomen and 25 cases for pelvic; These clinical datasets are not used in the training datasets at all.

(2) American public datasets (N=103);

(a)The 2017 lung CT segmentation challenge (LCTSC), which contains 60 thoracic CT scan patients with five segmented organs (left lung, right lung, heart, spinal cord, and esophagus), (b) Pancreas-CT (PCT), which contains 43 abdominal contrast enhanced CT scan patients with seven segmented organs (the spleen, left kidney, esophagus, liver, stomach, pancreas, and duodenum). The American public datasets were annotated by the American doctors. The article was published in the journal (Medical Physics), doi: 10.1002/mp.14131. (Please refer to more information about the two publicly available datasets: https://wiki.cancerimagingarchive.net/pages/viewpage.action?pageId=24284539, https://wiki.cancerimagingarchive.net/display/Public/Pancreas-CT)

The auto-segmentation process is the same with what was applied to the training dataset with two steps: first step to distinguish the four different regions (head and neck region, chest region, abdomen region and pelvic region), second step to call the model of this region to realize auto-segmentation. The ground truth annotations for the 100 cases in China were established by two different radiation oncologists with more than 10 years of clinical practice (See Appendix 2 for their detailed CVs) following RTOG and clinical guidelines using manual annotation. A third qualified internal staff member is also available to adjudicate if needed. American public datasets (N=103) were annotated by the American doctors.

The CT images in the 100 test cases were curated for suitability and to avoid bias through rich pre-processing and post-processing methods. Due to the differences between patients and the differences in CT machine image data, the data augmentation was used during training to simulate possible data situations in clinical practice, thereby increasing the model's generalization ability. The strategy of first localization and then segmentation is also used to improve the accuracy of the model.

Table 3: Verification Data Information

# of Datasets	100	103
Data Origin	Peking Union Medical College Hospital	The 2017 lung CT segmentation challenge (LCTSC): 60 Pancreas-CT (PCT): 43
Sex	Male: 43 Female: 57	Unknow:103 (unknown due to data minimization on customer site)

Age	<50: 31 50-70: 46 >70: 23	Unknown:103 (unknown due to data minimization on customer site)
Body Region	Head and neck region: 25 chest region: 25 abdomen region: 25 pelvic region: 25	60 thoracic CT scan: 5 segmented organs (left lung, right lung, heart, spinal cord, and esophagus) 43 abdominal CT scan: 7 segmented organs (the spleen, left kidney, esophagus, liver, stomach, pancreas, and duodenum)
CT Scanner	Philips: 34 GE: 36 Simens: 30	Unknown 103 (unknown due to data minimization on customer site)

7.3 Rigid and deformable registration

The rigid and deformable registration methods are mainly used for contour mapping in the delineation of target areas and organs at risk. The following Table showed the results between planning CT images (moving image) and CBCT images (Fixed images), rpCT represents rigid planning CT, dpCT1 represents deformed planning CT with our algorithms, and dpCT2 represents deformed planning CT with predicate device. The metrics include the mean absolute error (MAE), root mean square error (RMSE), peak signal-to-noise ratio (PSNR), and structural similarity (SSIM).

Table 4: Rigid and deformable registration

	rpCT-CBCT	dpCT1- CBCT	dpCT2- CBCT
MAE(HU)	51.23±13.67	43.98±10.74	46.71±12.71
RMSE	121.09±30.23	117.58±28.22	127.96±30.76
PSNR	20.01±2.74	22.23±2.61	20.00±3.77
SSIM	0.623±0.084	0.680±0.050	0.685±0.055

7.4 Performance comparison

The mean and standard deviation of Dice coefficients was calculated for each organ in the subject device compared with the predicate device. The results of the subject device demonstrate equivalent or better performance compared to the predicate device when aggregate performance over all organs is considered with known limitations described in the labeling. Here equivalence is defined such that the lower bound of 95th percentile confidence interval of the subject device segmentation is greater than 0.1 Dice lower than the mean of predicate device segmentation.

Dice coefficients of 100 clinical datasets collected from multiple clinical regions across the Peking Union Medical College Hospital compared to the predicate device are presented here:

Table 5: Clinical performance comparison (Peking Union Medical College Hospital)

Structure:	DeepContour	AI-Rad CAI-Rad Companion Organs RT（K221305）	Contour ProtégéAI（K223774）
Brain	0.98±0.01(0.97)	0.93±0.11	0.98 ± 0.01
BrainStem	0.91±0.03(0.89)	0.90±0.02	0.82 ± 0.09
Cochlea_L	0.86±0.03(0.84)	0.84±0.03	0.27 ± 0.17
Cochlea_R	0.85±0.01(0.84)	0.86±0.07	0.29 ± 0.18
Eye_L	0.89±0.02(0.88)	0.81±0.06	0.87 ± 0.06
Eye_R	0.88±0.03(0.86)	0.89±0.13	0.87 ± 0.06
Lens_L	0.89±0.02(0.88)	0.85±0.05	0.61 ± 0.17
Lens_R	0.88±0.02(0.85)	0.81±0.12	0.63 ± 0.15
Larynx	0.88±0.03(0.83)	0.84±0.08	0.50 ± 0.16
Larynx_extend	0.92±0.02(0.91)	0.90±0.11	None
Mandible	0.95±0.02(0.91)	0.91±0.07	0.85 ± 0.07
Optic_Chiasm	0.88±0.03(0.82)	0.63±0.11	0.12 ± 0.11
OpticalNerve_L	0.86±0.04(0.79)	0.66±0.06	0.53 ± 0.13
OpticalNerve_R	0.89±0.02(0.81)	0.59±0.10	0.52 ± 0.12
OralCavity	0.92±0.03(0.89)	0.82±0.09	0.77 ± 0.12
OralCavity_WithGum	0.91±0.06(0.89)	0.71±0.06	None
Parotid_L	0.88±0.05(0.82)	0.80±0.15	0.80 ± 0.10
Parotid_R	0.86±0.03(0.81)	0.81±0.04	0.80 ± 0.06
Pituitary	0.78±0.04(0.69)	0.68±0.14	0.49 ± 0.15
Temporal_Lobe_L	0.92±0.02(0.90)	0.82±0.09	0.68 ± 0.17
Temporal_Lobe_R	0.91±0.11(0.86)	0.81±0.07	0.79 ± 0.18
TMJ_L	0.85±0.02(0.83)	0.84±0.02	0.84± 0.06

TMJ_R	0.86±0.15(0.81)	0.85±0.15	0.83 ± 0.06
InternalAcousticCanal_L	0.76±0.02(0.71)	0.73±0.12	0.71 ± 0.17
InternalAcousticCanal_R	0.79±0.02(0.75)	0.77±0.05	0.73 ± 0.15
MiddleEar_L	0.82±0.12(0.78)	0.72±0.02	0.70 ± 0.16
MiddleEar_R	0.85±0.03(0.81)	0.80±0.13	0.77 ± 0.17
TemporalLobe_withHippo_L	0.89±0.08(0.85)	0.87±0.14	0.85 ± 0.18
TemporalLobe_withHippo_R	0.90±0.05(0.86)	0.88±0.09	0.87 ± 0.06
Submandibular_L	0.91±0.06(0.88)	0.81±0.11	0.75 ± 0.10
Submandibular_R	0.92±0.03(0.89)	0.72±0.16	0.74 ± 0.09
PharyngealConstrictors_U	0.82±0.12(0.76)	0.77±0.13	None
PharyngealConstrictors_M	0.86±0.14(0.83)	0.76±0.11	None
PharyngealConstrictors_L	0.84±0.17(0.80)	0.74±0.07	None
BrachialPlexus_L	0.81±0.13(0.79)	0.71±0.08	0.37 ± 0.13
BrachialPlexus_R	0.82±0.11(0.69)	0.52±0.06	0.36 ± 0.16
Hippocampus_L	0.76±0.03(0.73)	0.75 ± 0.12	0.75 ± 0.02
Hippocampus_R	0.79±0.02(0.76)	0.73 ± 0.09	0.76 ± 0.02
EustachianTubeBone_L	0.85±0.05(0.84)	0.81±0.05	0.88 ± 0.07
EustachianTubeBone_R	0.87±0.07(0.80)	0.77±0.09	0.72 ± 0.17
TympanicCavity_L	0.84±0.03(0.83)	0.80±0.13	0.75 ± 0.15
TympanicCavity_R	0.86±0.09(0.81)	0.76±0.05	0.74 ± 0.17
Vestibule_L	0.85±0.06(0.82)	0.80±0.16	0.79 ± 0.10
Vestibule_R	0.87±0.02(0.86)	0.77±0.10	0.74 ± 0.10
InnerEar_L	0.87±0.10(0.83)	0.83±0.11	0.82 ± 0.07
InnerEar_L	0.86±0.13(0.83)	0.87±0.03	0.91 ± 0.07
Lung_L	0.98±0.05(0.96)	0.92±0.16	0.96 ± 0.02

Lung_R	0.99±0.03(0.98)	0.95±0.08	0.96 ± 0.02
Lung_All	0.98±0.14(0.97)	0.91±0.04	None
Heart	0.93±0.16(0.90	0.91±0.06	0.90 ± 0.07
Trachea	0.89±0.03(0.88)	0.89±0.03	0.73 ± 0.17
Esophagus	0.88±0.11(0.85)	0.78±0.07	0.70 ± 0.15
Breast_L	0.92±0.08(0.86)	0.82±0.05	0.74 ± 0.17
Breast_R	0.93±0.01(0.92)	0.83±0.04	0.77 ± 0.10
Aorta	0.89±0.09(0.87)	0.70 ± 0.08	0.74 ± 0.10
Liver	0.96±0.07(0.95)	0.86±0.17	0.93 ± 0.07
Kidney_L	0.92±0.03(0.91)	0.82±0.13	0.92 ± 0.05
Kidney_R	0.93±0.04(0.91)	0.88±0.07	0.91 ± 0.06
Duodenum	0.88±0.16(0.83)	0.81±.012	None
Pancreas	0.86±0.01(0.86)	0.87±0.03	0.45 ± 0.22
Smallintestine	0.89±0.12(0.85)	0.88±0.08	None
Bowelbag	0.93±0.16(0.88)	0.83 ± 0.08	0.68 ± 0.08
Bladder	0.95±0.15(0.93)	0.87 ± 0.15	0.52 ± 0.19
Stomach	0.86±0.01(0.86)	0.79 ± 0.21	0.81 ± 0.11
Femur_Head_L	0.92±0.12(0.89)	0.90±0.16	0.93 ± 0.05
Femur_Head_R	0.91±0.14(0.86)	0.90±0.09	0.93 ± 0.04
Pelvis	0.87±0.01(0.87)	0.88±0.08	0.93 ± 0.11
Marrow	0.85±0.13(0.84)	0.81±0.03	None
Sigmoid	0.82±0.02(0.81)	0.70 ± 0.17	0.60 ± 0.26
Rectum	0.87±0.15(0.83)	0.73 ± 0.18	0.83 ± 0.11
Spleen	0.91±0.01(0.90)	0.92±0.07	0.95 ± 0.03
SeminalVesicle	0.86±0.02(0.85)	0.78 ± 0.27	0.68 ± 0.15
Testis	0.87±0.03(0.84)	0.79 ± 0.16	0.63 ± 0.16
Prostate	0.87±0.02(0.85)	0.74 ± 0.12	0.85 ± 0.06

Ovid_L	0.85±0.03(0.82)	0.65±0.03	0.39 ± 0.17
Ovid_R	0.86±0.01(0.85)	0.66±0.01	0.43 ± 0.15
Bladder-Brt	0.86±0.02(0.84)	0.82 ± 0.23	0.91 ± 0.12
SmallIntestine-Brt	0.87±0.04(0.85)	0.76 ± 0.14	0.73 ± 0.11
Rectum-Brt	0.86±0.03(0.84)	0.85 ± 0.18	0.83 ± 0.11
Sigmoid-Brt	0.79±0.02(0.78)	0.70 ± 0.17	0.60 ± 0.26
SpinalCord	0.93±0.01(0.92)	0.66 ± 0.14	0.63 ± 0.16
Body	0.98±0.05(0.96)	0.97±0.03	None

Data format: Mean ± Std Dice coefficient (lower 95th percentile confidence bound based on normal distribution in parentheses)

Dice coefficients of LCTSC American public datasets compared to the predicate device are presented here:

Table 6: Clinical performance comparison (LCTSC American public datasets)

Structure:	DeepContour	AI-Rad CAI-Rad Companion Organs RT （K221305）	Contour ProtégéAI （K223774）
SpinalCord	0.92±0.02(0.91)	0.64±0.13	0.62 ± 0.21
Lung L	0.97±0.15(0.96)	0.90±0.13	0.95 ± 0.05
Lung R	0.98±0.06(0.98)	0.93±0.11	0.94 ± 0.08
Heart	0.92±0.11(0.90)	0.91±0.04	0.90 ± 0.04
Esophagus	0.89±0.13(0.86)	0.75±0.13	0.68 ± 0.19

Data format: Mean ± Std Dice coefficient (lower 95th percentile confidence bound based on normal distribution in parentheses)

Dice coefficients of Pancreas-CT American public datasets compared to the predicate device are presented here:

Table 7: Clinical performance comparison (Pancreas-CT American public datasets)

Structure:	DeepContour	AI-Rad CAI-Rad Companion Organs RT （K221305）	Contour ProtégéAI （K223774）
Spleen	0.90±0.05(0.88)	0.91±0.12	0.89 ± 0.08
Pancreas	0.85±0.03(0.83)	0.84±0.02	0.43 ± 0.25
Kidney_L	0.93±0.02(0.91)	0.84±0.03	0.92 ± 0.17
Esophagus	0.88±0.02(0.87)	0.80±0.06	0.70 ± 0.06
Liver	0.97±0.03(0.97)	0.85±0.13	0.92 ± 0.06
Stomach	0.85±0.02(0.84)	0.80±0.05	0.81 ± 0.17
Duodenum	0.86±0.02(0.85)	0.82±0.12	None

Data format: Mean ± Std Dice coefficient (lower 95th percentile confidence bound based on normal distribution in parentheses)

A comparison of the median Average Symmetric Surface Distance (ASSD) between the subject device and the predicate device is also performed and the results are comparable as shown in the following table. The subject device achieved a median ASSD of 0.95 in comparison to the predicate device achieving a median ASSD of 0.96 for existing organs.

Table 8: Rigid and deformable registration

	DeepContour		AI-Rad CAI-Rad Companion Organs RT （K221305）		Contour ProtégéAI （K223774）	
	Median	95% CI (Bootstrap)	Median	95% CI (Bootstrap)	Median	95% CI (Bootstrap)
ASSD	0.95	[0.85,1.13]	0.96	[0.84,1.15]	0.95	[0.86,1.17]

8 CONCLUSION

DeepContour is believed to be substantially equivalent to predicate device in terms of its indications for use, technical characteristics, and overall performance. The information provided in this submission indicates the subject device is as safe, is as effective, and performs as well as predicate device. Therefore, it is in the opinion of Wisdom Technologies, Inc. that the medical device, DeepContour, is substantially equivalent to predicate device.