Coreline Soft Co., Ltd.
℅ Hyeyi Park
RA Manager
4,5F (Yeonnam-dong), 49,
World Cup buk-ro-6-gil,
Mapo-gu, Seoul, 03991
REPUBLIC OF KOREA

November 10, 2022

Re: K220408
Trade/Device Name: AVIEW RT ACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QKB
Dated: October 7, 2022
Received: October 11, 2022

Dear Hyeyi Park:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Julie Sullivan -S

Julie Sullivan, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220408

Device Name

AVIEW RT ACS

Indications for Use *(Describe)*

AVIEW RT ACS provides deep-learning-based auto-segmented organs and generates contours in RT-DICOM format from CT images which could be used as an initial contour for the clinicians to approve and edit by the radiation oncology department for treatment planning or other professions where a segmented mask of organs is needed.

a. Deep learning contouring from four body parts (Head & Neck, Breast, Abdomen, and Pelvis)
b. Generates RT-DICOM structure of contoured organs
c. Rule-based auto pre-processing

Receive/Send/Export medical images and DICOM data

Note that the Breast (Both right and left lung, Heart) were validated with non-contrast and contrast CT. Head & Neck (Both right and left Eyes, Brain and Mandible), Abdomen (Both right and left Kidney and Liver), and Pelvis (Both right and left Femur and Bladder) were validated with Contrast CT only.

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

K220408

1 SUBMITTER

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Fax: 82.2.571.7324

Contact Person: hyeyi. Park
Date Prepared: 02.10.2022

2 DEVICE

Name of Device: AVIEW RT ACS
Common or Usual Name: Medical Imaging Software
Classification Name: Radiological Image Processing Software For Radiation Therapy (21CFR 892.2050)
Regulatory Class: II
Product Code: QKB

3 PREDICATE DEVICE

MIM-MRT Dosimetry by MIM Software Inc. (K182624)

Name of Device: MIM-MRT Dosimetry
Common or Usual Name: Medical Imaging Software
Classification Name: System, image processing, radiological (21CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

This predicate has not been subject to a design-related recall

4 REFERENCE DEVICE

AccuContour™ by Xiamen Manteia Technology LTD. (K191928)

Name of Device: AccuContour™
Common or Usual Name: Medical Imaging Software
Classification Name: Radiological Image Processing Software For Radiation Therapy (21CFR 892.2050)
Regulatory Class: II
Product Code: QKB

This reference device has not been subject to a design-related recall

5 DEVICE DESCRIPTION

The AVIEW RT ACS provides deep-learning-based auto-segmented organs and generates contours in RT-DICOM format from CT images. This software could be used by the radiation oncology department for treatment planning, or other professions where a segmented mask of organs is needed.

- Deep learning contouring: it can automatically contour the organ-at-risk (OARs) from four body parts (Head & Neck, Breast, Abdomen, and Pelvis)
- Generates RT-DICOM structure of contoured organs
- Rule-based auto pre-processing

Receive/Send/Export medical images and DICOM data

6 INDICATIONS FOR USE

AVIEW RT ACS provides deep-learning-based auto-segmented organs and generates contours in RT-DICOM format from CT images which could be used as an initial contour for the clinicians to approve and edit by the radiation oncology department for treatment planning or other professions where a segmented mask of organs is needed.

a. Deep learning contouring from four body parts (Head & Neck, Breast, Abdomen, and Pelvis)
b. Generates RT-DICOM structure of contoured organs
c. Rule-based auto pre-processing

Receive/Send/Export medical images and DICOM data

Note that the Breast (Both right and left lung, Heart) were validated with non-contrast and contrast CT. Head & Neck (Both right and left Eyes, Brain, and Mandible), Abdomen (Both right and left Kidney and Liver), and Pelvis (Both right and left Femur and Bladder) were validated with Contrast CT only.

8 COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCIE

AVIEW RT ACS has the same intended use and the principle of operation and has similar features to the predicate devices.

There might be slight differences in features and menu, but these differences between the predicate device and the proposed device are not so significant since they do not raise any new or potential safety risks to the user or patient and questions of safety or effectiveness. Based on the results of software validation and verification tests, we conclude that the proposed device is substantially equivalent to the predicate devices.

Characteristic	Subject Device	Primary Predicate Device	Reference Device
Device Name	**AVIEW RT ACS**	**MIM-MRT Dosimetry**	**AccuContour**
Classification Name	Radiological Image Processing Software For Radiation Therapy	System, image Processing Radiological	Radiological Image Processing Software For Radiation Therapy
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Product Code	QKB	LLZ	QKB
Review Panel	Radiology	Radiology	Radiology
510k Number	-	K182624	K191928
Indications for use	**AVIEW RT ACS** AVIEW RT ACS provides deep-learning-based auto-segmented organs and generates contours in RT-DICOM format from CT images which could be used as an initial contour for the clinicians to approve and edit by the radiation oncology department for treatment planning or other professions where a segmented mask of organs is needed. a. Deep learning contouring from four body parts (Head & Neck, Breast, Abdomen, and Pelvis) b. Generates RT-DICOM structure of contoured organs c. Rule-based auto pre-processing Receive/Send/Export medical images and DICOM data Note that the Breast (Both right and left lung, Heart) were validated with non-contrast and contrast CT. Head & Neck (Both right and left Eyes, Brain and Mandible), Abdomen (Both right and left Kidney and Liver), and Pelvis (Both right and left Femur and Bladder) were validated with Contrast CT only.		
	MIM-MRT Dosimetry MIM software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM assists in the following indications: • Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects. • Create, display and print reports from medical images. • Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning. • Evaluation of cardiac left ventricular function and perfusion, including left ventricular enddiastolic volume, end-systolic volume, and ejection fraction. • Localization and definition of objects such as tumors and normal tissues in medical images. • Creation, transformation, and modification of contours 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. • Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans. • Planning and evaluation of permanent implant brachytherapy procedures (not including radioactive microspheres). • Calculating absorbed radiation dose as a result of administering radionuclide. When using device clinically, the user should only use FDA approved radiopharmaceuticals. If using with unapproved ones, this device should only be used for research purposes. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Images that are printed to film must be printed using an FDA-approved printer for the diagnosis of digital mammography images. Mammographic images must be viewed on a display system that has been cleared by the FDA for the diagnosis of digital mammography images. The software is not to be used for mammography CAD.
	AccuContour
	It is used by radiation oncology department to register multimodality images and segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation.
General Description	**AVIEW RT ACS**
	The AVIEW RT ACS provides deep-learning-based auto-segmented organs and generates contours in RT-DICOM format from CT images. This software could be used by the radiation oncology department for treatment planning, or other professions where a segmented mask of organs is needed. • Deep learning contouring: it can automatically contour the organ-at-risk (OARs) from four body parts (Head & Neck, Breast, Abdomen, and Pelvis) • Generates RT-DICOM structure of contoured organs • Rule-based auto pre-processing Receive/Send/Export medical images and DICOM data
	MIM-MRT Dosimetry
	MIM - MRT Dosimetry extends features of MIM SurePlan. It is designed for use in medical imaging and operates on both Windows and Mac computer systems. MIM - MRT Dosimetry extends the functionality of the MIM - Y90 Dosimetry (K172218) software and utilizes functionality of MIM –SPECTRA Quant (K180815). Both of these are predicates for this submission. The following functions have been added to allow calculations of absorbed dose as a result of administering a radionuclide. • Allows for quantification of planar images • Allows for calculation of time-integrated activity coefficients • Allows for voxel-based dose calculation of radionuclides Allows for correction of dose for tissue density
	AccuContour
	The proposed device, AccuContourTM, is a standalone software which is used by radiation oncology department to register multimodality images and segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation. The product has two image process functions: (1) Deep learning contouring: it can automatically contour the organ-at-risk, including head and neck, thorax, abdomen and pelvis (for both male and female), (2) Automatic Registration, and (3) Manual Contour. It also has the following general functions: • Receive, add/edit/delete, transmit, input/export, medical images and DICOM data.

	• Patient management. • Review of processed images. Open and save of files.		
Operating System	Windows	Windows and MAC system	Windows
Image format	DICOM	DICOM	DICOM
Data Communications	Receive, transmit, store, retrieve and process medical images and DICOM objects	Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects.	Receive, add/edit/delete, transmit, input/export, medical images and DICOM data
Algorithm	Deep Learning	Atlas-based	Deep Learning
Compatible Modality	CT Images	Non-Contrast CT	Non-Contrast CT
Segmentation of Organ	Head & Neck, Breast, Abdomen, Pelvis	Head & Neck, Breast, Abdomen, Pelvic	Head & Neck, Thorax, Abdomen & Pelvis
Automated workflow	Automatically processes input image data contour organs and DICOM sends generated RT Structure set	Creation, transformation, and modification of contours 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	AccuContour automatically processes input image data
Data anonymization	Replaces the patient's name and ID with user defined prefix and suffixes and IDs and strips the birth date, referring physician name, and any private DICOM tags that exist.	Replaces the patient's name and ID with randomized generic names and IDs and strips the birth date, referring physician name, and any private DICOM tags that exist.	No information publicly available.
Target Population	Any patient type for whom scanned with CT modality images and segment CT images are available.	Any patient type for whom relevant modalities such as CT and MR, as supported by ACR/NEMA DICOM 3.0.	Any patient type for whom Relevant multimodality images and segment (non-contrast) CT images are available.
Segmentation Performance	The segmentation performance was validated multi-race and multi-vendor using datasets from South Korea and the USA using four major vendors (GE, Siemens, Toshiba and Phillips). The segmentation accuracy is evaluated using DICE coefficient	Contour Evaluation: Atlas-based segmentation studies have shown the accuracy of multi-atlas segmentation with an overall average dice similarity index of 0.81 for the contours tested: right and left lung, trachea, heart, and esophagus	The segmentation performance was validated using datasets from China and the USA using three major vendors (GE, Siemens and Phillips). The segmentation accuracy is evaluated using DICE coefficient

9 PERFORMANCE DATA

9.1 Handware and software verification and Validation

This Medical device is not new; therefore, a clinical study was not considered necessary prior to release. Additionally, there was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing

Verification, validation, and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.

- Unit Test
  Conducting Unit Test using Google C++ Unit Test Framework on major software components identified by software development team. List of Unit Test includes Functional test condition for software component unit, Performance test condition, and part of algorithm analysis for image processing algorithm.

- System Test
  In accordance with the document 'integration Test Cases' discussed in advanced by software development team and test team, test is conducted by installing software to hardware with recommended system specification. Despite Test case recognized in advance was not in existence. New software error discovered by 'Exploratory Test' conducted by test team will be registered and managed as new test case after discussion between development team and test team.
  Discovered software error will be classified into 3 categories as severity and managed.
    - ✓ Major defects, which are impacting the product's intended use and no workaround is available.
    - ✓ Moderate defects, which are typically related to user-interface or general quality of product, while workaround is available.
    - ✓ Minor defects, which aren't impacting the product's intended use. Not significant.

  Success standard of System Test is not finding 'Major', 'Moderate' defect.

- Performance Test
    - DICOM Test Report
    - DICOM Conformance Statement
    - Thin Client Server Compatibility Test Report
    - Compare Standalone Performacne Test
        - The purpose of this test is to compare and verify the AVIEW RT ACS performance and the performance of the predicate device. The test process involves generating a robust gold standard. Three radiation oncology physicians segmented the organs to be used for validation. There were 3 experts, all trained by the "The Korean Society for Radiation Oncology", board-certified by the "Ministry of Health and Welfare", with a range of 9–21 years of experience in radiotherapy to participate in this test. The experts were attending assistant professors (n=2), and professors (n=1) from three institutions. First, the 1 expert manually delineated the organs. Second, segmentation results generated by 1 expert are sequentially edited by 2 experts. In the editing process, the first expert makes corrections, and the result is received by another expert. The final expert completes the gold standard by finalizing it. This process was performed by a panel of three radiation oncology physicians' experiences. And the results of auto-segmentation of gold-standard and AVIEW RT ACS and auto-segmentation of predicate device are analyzed and evaluated using

DSC and 95% HD, respectively.The data set information used in the test is 120cases (each 60cases) including both Korean and U.S, Gender: F 70, M 50, Age: 20-89 years. The TCIA data was constructed with various ethnics (White, Black, Asian, Hispanic, Latino, African, American, etc.), the result can be obtained by performing generalization without performance difference according to ethnic

- Breast (Both right and left lung, Heart) were validated with non-contrast and contrast CT.
- Head & Neck(Both right and left Eyes, Brain and Mandible), Abdomen(Both right and left Kidney and Liver), and Pelvis(Both right and left Femur and Bladder) were validated with Contrast CT only.
- DSC and 95% HD(mm) for
  - ◆ Total DSC & HD analysis.
    - Table 1 DSC for each oragn

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (25)	0.97 ± 0.01(0.97, 0.98)	0.96 ± 0.01 (0.96, 0.96)	0.01
	Rt. Eye (25)	0.79 ± 0.10 (0.75, 0.83)	0.80 ± 0.06 (0.77, 0.82)	-0.01
	Lt. eye (25)	0.72 ± 0.12 (0.67, 0.76)	0.76 ± 0.12 (0.72, 0.81)	-0.04
	Mandible (25)	0.90 ± 0.05 (0.89, 0.93)	0.83 ± 0.07 (0.80, 0.86)	0.07
Breast	Heart (32)	0.94 ± 0.03 (0.93, 0.95)	0.78 ± 1.20 (0.70, 8.56)	0.16
	Rt. Lung (31)	0.98 ± 0.01 (0.97, 0.98)	0.96 ± 0.02 (0.95, 0.97)	0.02
	Lt. Lung (31)	0.97 ± 0.02 (0.96, 0.98)	0.96 ± 0.03 (0.95, 0.97)	0.01
Abdom en	Liver (26)	0.96 ± 0.01 (0.96, 0.97)	0.87 ± 0.06 (0.85, 0.90)	0.09
	Rt. Kidney (26)	0.90 ± 0.03 (0.89, 0.91)	0.75 ± 0.18 (0.68, 0.82)	0.15
	Lt. kidney (26)	0.90 ± 0.05 (0.88, 0.92)	0.79 ± 0.12 (0.75, 0.84)	0.11
Pelvis	Bladder (35)	0.88 ± 0.14 (0.84, 0.93)	0.52 ± 0.26 (0.44, 0.60)	0.36
	Rt. Femur head (37)	0.87 ± 0.14 (0.83, 0.90)	0.58 ± 0.11 (0.54, 0.61)	0.29
	Lt. Femur head (37)	0.86 ± 0.10 (0.83, 0.90	0.55 ± 0.11(0.51, 0.58)	0.31

    - Table 2. 95% HD (mm) for each oragn

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (25)	6.92 ± 20.46 (-1.1, 14.94)	4.61 ± 2.17 (3.76, 5.46)	2.31
	Rt. Eye (25)	3.68 ± 1.50 (3.09, 4.27)	4.38 ± 1.36 (3.85, 4.91)	-0.70
	Lt. eye (25)	6.38 ± 11.11 (2.03, 10.74)	7.74 ± 10.83 (3.50, 11.99)	-1.36
	Mandible (25)	2.01 ± 1.23 (1.53, 2.49)	24.00 ± 93.61 (-12.69, 60.70)	-21.99
Breast	Heart (32)	6.19 ± 4.21 (4.73, 7.65)	18.90 ± 5.09 (17.14, 20.67)	-12.71
	Rt. Lung (31)	2.88 ± 1.67 (2.30, 3.47)	7.03 ± 2.94 (6.00, 8.06)	-4.14
	Lt. Lung (31)	4.97 ± 13.49 (0.22, 9.72)	4.83 ± 6.21 (2.64, 7.02)	0.14
Abdom en	Liver (26)	7.17 ± 12.07 (2.54, 11.81)	24.62 ± 15.16 (18.79, 30.44)	-17.44
	Rt. Kidney (26)	6.84 ± 9.14 (3.33, 10.35)	14.63 ± 13.07 (9.60, 19.65)	-7.79

	Lt. kidney (26)	5.34 ± 4.30 (3.69, 6.99)	15.18 ± 10.71 (11.06, 19.26)	-9.84
Pelvis	Bladder (35)	10.55 ± 20.56 (3.74, 17.36)	30.48 ± 22.76 (22.94, 38.02)	-19.93
	Rt. Femur head (37)	10.02 ± 8.94 (7.10, 12.93)	43.65 ± 30.38 (33.72, 53.57)	-33.63
	Lt. Femur head (37)	11.75 ± 12.42 (7.64, 15.86)	46.14 ± 24.84 (37.91, 54.37)	-34.39

DSC and 95% HD(mm) were obtained by race, vendors, slice thickness and kernel for sub-group analysis.

◆ Dice Similarity Coefficient Comparison (DSC)

- Table 3. DSC for Korean Population each organ.

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (10)	0.97 ± 0.01 (0.97, 0.98)	0.96 ± 0.01 (0.95, 0.96)	0.01
	Rt. Eye (10)	0.81 ± 0.07 (0.76, 0.86)	0.80 ± 0.07 (0.76, 0.84)	0.01
	Lt. eye (10)	0.77 ± 0.09 (0.71, 0.82)	0.79 ± 0.06 (0.75. 0.83)	-0.02
	Mandible (10)	0.90 ± 0.03 (0.89, 0.93)	0.81 ± 0.09 (0.76, 0.87)	0.09
Breast	Heart (21)	0.95 ± 0.02 (0.94, 0.96)	0.81 ± 0.10 (0.76, 0.85)	0.14
	Rt. Lung (21)	0.97 ± 0.01 (0.97, 0.98)	0.96 ± 0.02 (0.95, 0.97)	0.01
	Lt. Lung (21)	0.96 ± 0.02 (0.96, 0.97)	0.95 ± 0.03 (0.94, 0.97)	0.01
Abdomen	Liver (10)	0.95 ± 0.01 (0.94, 0.96)	0.88 ± 0.08 (0.83, 0.93)	0.07
	Rt. Kidney (10)	0.89 ± 0.03 (0.87, 0.91)	0.75 ± 0.24 (0.60, 0.90)	0.14
	Lt. kidney (10)	0.88 ± 0.06 (0.84, 0.92)	0.80 ± 0.16 (0.70, 0.90)	0.08
Pelvis	Bladder (17)	0.92 ± 0.07 (0.89, 0.95)	0.47 ± 0.27 (0.34, 0.59)	0.45
	Rt. Femur head (19)	0.88 ± 0.07 (0.84, 0.91)	0.56 ± 0.11 (0.51, 0.61)	0.32
	Lt. Femur head (19)	0.87 ± 0.78 (0.84, 0.91)	0.52 ± 0.13 (0.46, 0.58)	0.35

- Table 4. DSC for U.S Population each organ.

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (15)	0.97 ± 0.01 (0.96, 0.98)	0.96 ± 0.01 (0.96, 0.97)	0.01
	Rt. Eye (15)	0.78 ± 0.12 (0.72, 0.84)	0.80 ± 0.06 (0.77, 0.83)	-0.02
	Lt. eye (15)	0.68 ± 0.13 (0.62 ± 0.75)	0.75 ± 0.14 (0.68, 0.82)	-0.07
	Mandible (15)	0.91 ± 0.06 (0.88, 0.94)	0.84 ± 0.06 (0.81, 0.87)	0.07
Breast	Heart (11)	0.93 ± 0.04 (0.90, 0.95)	0.71 ± 0.09 (0.65, 0.76)	0.22
	Rt. Lung (10)	0.98 ± 0.0 (0.98, 0.99)	0.96 ± 0.01 (0.96, 0.97)	0.02
	Lt. Lung (10)	0.97 ± 0.03 (0.95, 0.99)	0.96 ± 0.03 (0.95. 0.98)	-0.01
Abdomen	Liver (16)	0.97 ± 0.01 (0.96, 0.97)	0.87 ± 0.05 (0.85, 0.90)	1.0
	Rt. Kidney (16)	0.91 ± 0.01 (0.91, 0.92)	0.75 ± 0.14 (0.68. 0.82)	0.16

	Lt. kidney (16)	0.91 ± 0.02 (0.90, 0.92)	0.79 ± 0.09 (0.74, 0.83)	0.12
Pelvis	Bladder (18)	0.85 ± 0.19 (0.76, 0.94)	0.58 ± 0.22 (0.48, 0.69)	0.27
	Rt. Femur head (18)	0.80 ± 0.12 (0.80, 0.91)	0.60 ± 0.10 (0.55, 0.65)	0.20
	Lt. Femur head (18)	0.85 ± 0.13 (0.79 ± 0.91)	0.57 ± 0.09 (0.53, 0.62)	0.27

◆ Hausdorff Distance Comparison (95% HD)

- Table 5. 95% HD (mm) for Korean Population each organ.

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (10)	13.19 ± 32.27 (6.81, 33.19)	4.33 ± 1.33 (3.51, 5.16)	8.86
	Rt. Eye (10)	3.18 ± 1.01 (2.55, 3.81)	4.14 ± 1.36 (3.30, 4.99)	-0.96
	Lt. eye (10)	3.53 ± 1.40 (2.66, 4.40)	5.22 ± 2.33 (3.78, 6.66)	-1.69
	Mandible (10)	2.02 ± 0.53 (1.69, 2.35)	6.15 ± 5.71 (2.61, 9.69)	-4.13
Breast	Heart (21)	5.24 ± 2.57 (4.15, 6.34)	18.16 ± 4.72 (16.14, 20.18)	-12.92
	Rt. Lung (21)	3.41 ± 1.76 (2.66, 4.16)	6.87 ± 3.19 (5.50, 8.23)	-3.46
	Lt. Lung (21)	2.79 ± 0.52 (2.57, 3.01)	3.24 ± 0.96 (2.83, 3.65)	-0.45
Abdomen	Liver (10)	4.29 ± 1.50 (3.26, 5.22)	21.14 ± 17.22 (10.46, 31.81)	-16.85
	Rt. Kidney (10)	4.74 ± 1.77 (3.65, 5.84)	15.24 ± 17.44 (4.43, 26.05)	-10.49
	Lt. kidney (10)	6.24 ±3.35 (2.30, 10.18)	12.34 ± 10.54 (5.80, 18.87)	-6.10
Pelvis	Bladder (17)	4.90 ± 6.03 (2.19, 7.61)	33.96 ± 26.33 (22.13, 45.80)	-29.06
	Rt. Femur head (19)	9.52 ± 6.64 (6.61, 12.43)	41.34 ± 8.74 (37.51, 45.17)	-31.82
	Lt. Femur head (19)	9.93 ± 6.83 (6.94, 12.92)	49.19 ± 32.97 (34.73, 63.64)	-39.26

- Table 6. 95% HD (mm) for U.S Population each organ

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (15)	2.74 ± 1.09 (2.19, 3.29)	4.79 ± 2.62 (3.47, 6.12)	-2.05
	Rt. Eye (15)	4.01 ± 1.71 (3.15, 4.87)	4.53 ± 1.38 (3.84, 5.23)	-0.52
	Lt. eye (15)	8.29 ± 14.16 (1.12, 15.45)	9.42 ± 13.78 (2.45, 16.40)	-1.13
	Mandible (15)	2.00 ± 1.56 (1.21, 2.79)	35.91 ± 120.91 (-25.28, 97.10)	-33.91
Breast	Heart (11)	8.00 ± 6.03 (4.43, 11.56)	20.31 ± 5.71 (16.94, 23.69)	-12.31
	Rt. Lung (10)	1.78 ± 0.66 (1.36, 2.19)	7.37 ± 2.43 (5.86, 8.88)	-5.59
	Lt. Lung (10)	9.56 ± 23.90 (-5.25, 24.97)	8.18 ± 10.41 (1.72, 14.63)	1.38
Abdomen	Liver (16)	8.98 ± 15.24 (1.51, 16.45)	26.79 ± 13.86 (20.00, 33.58)	-17.81
	Rt. Kidney (16)	8.15 ± 11.51 (3.61, 5.94)	14.25 ± 10.08 (9.31, 19.19)	-6.10
	Lt. kidney (16)	4.77 ± 2.38 (3.61, 5.94)	16.96 ± 10.75 (11.69, 22.22)	-12.19

Pelvis	Bladder (18)	17.37 ± 28.73 (3.29, 31.44)	27.01 ± 18.47 (17.96, 36.06)	-9.64
	Rt. Femur head (18)	10.57 ± 11.16 (5.10, 16.04)	46.09 ± 43.22 (24.91, 67.27)	-35.52
	Lt. Femur head (18)	13.91 ± 16.86 (5.38, 22.44)	42.52 ± 8.23 (38.35, 46.68)	-28.61

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◆ DSC & 95% HD (mm) Comparison by vendors, slice thickness and kernel

- Table 7. DSC for organ by SIEMENS vendors.

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (4)	0.97 ± 0.01 (0.97. 0.98)	0.96 ± 0.0 (0.96, 0.97)	0.01
	Rt. Eye (4)	0.85 ± 0.05 (0.80, 0.90)	0.77 ± 0.05 (0.72, 0.82)	0.08
	Lt. eye (4)	0.78 ± 0.04 (0.71, 0.86)	0.77 ± 0.05 (0.72, 0.82)	0.01
	Mandible (4)	0.91 ± 0.04 (0.87, 0.94)	0.81 ± 0.13 (0.68, 0.94)	0.10
Breast	Heart (9)	0.94 ± 0.02 (0.93, 0.96)	0.75 ± 0.10 (0.69, 0.82)	0.19
	Rt. Lung (9)	0.97 ± 0.01 (0.96, 0.98)	0.95 ± 0.02 (0.94, 0.97)	-0.02
	Lt. Lung (9)	0.96 ± 0.02 (0.95, 0.97)	0.95 ± 0.02 (0.94, 0.97)	0.01
Abdomen	Liver (16)	0.96 ± 0.01 (0.96, 0.97)	0.86 ± 0.06 (0.84, 0.89)	0.10
	Rt. Kidney (16)	0.91 ± 0.02 (0.90, 0.92)	0.77 ± 0.12 (0.72, 0.83)	0.14
	Lt. kidney (16)	0.91 ± 0.03 (0.89, 0.92)	0.78 ± 0.08 (0.74, 0.82)	0.13
Pelvis	Bladder (18)	0.90 ± 0.07 (0.87, 0.93)	0.55 ± 0.27 (0.42, 0.67)	0.35
	Rt. Femur head (19)	0.90 ± 0.06 (0.87, 0.93)	0.56 ± 0.10 (0.51, 0.60)	0.34
	Lt. Femur head (19)	0.89 ± 0.09 (0.85, 0.93)	0.53 ± 0.13 (0.47, 0.58)	0.36

- Table 8. 95% HD (mm) for each organ by SIEMENS vendors.

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (4)	28.16 ± 51.23 (-22.04, 78.36)	3.28 ± 0.45 (2.84, 3.72)	24.88
	Rt. Eye (4)	2.77 ± 0.37 (2.42, 3.13)	4.75 ± 1.50 (3.29, 6.22)	-1.98
	Lt. eye (4)	3.26 ± 0.53 (2.74, 3.78)	5.30 ± 2.18 (3.16 ± 7.44)	-2.04
	Mandible (4)	1.91 ± 0.51 (1.42, 2.41)	5.04 ± 4.11 (1.01, 9.08)	-3.13
Breast	Heart (9)	5.92 ± 2.97 (3.98, 7.86)	20.17 ± 3.52 (17.86, 22.47)	-14.25
	Rt. Lung (9)	2.73 ± 0.61 (2.33, 3.13)	7.30 ± 2.63 (5.58, 9.02)	-4.58
	Lt. Lung (9)	2.97 ± 0.26 (2.80, 3.14)	3.63 ± 1.25 (2.81, 4.45)	-0.65
Abdomen	Liver (16)	9.10 ± 15.19 (1.66, 16.55)	29.04 ± 14.54 (21.92, 36.16)	-19.93
	Rt. Kidney (16)	8.40 ± 11.42 (2.81, 14.00)	15.54 ± 9.83 (10.73, 20.36)	-7.14
	Lt. kidney (16)	5.47 ± 3.29 (3.86, 7.08)	18.94 ± 10.02 (14.03, 23.85)	-13.47
Pelvis	Bladder (18)	7.04 ± 9.22 (2.65, 11.42)	23.99 ± 17.93 (15.71, 32.27)	-16.95
	Rt. Femur head (19)	8.01 ± 6.47 (5.10, 10.92)	50.42 ± 3.59 (32.13, 68.71)	-42.41
	Lt. Femur head (19)	8.57 ± 7.05 (5.40, 11.74)	41.98 ± 9.27 (37.70, 46.27)	-33.41

- Table 9. DSC for each oragn by GE vendors

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (2)	0.96 ± 0.01 (0.96, 0.97)	0.97 ± 0.0 (0.96, 0.97)	-0.01
	Rt. Eye (2)	0.70 ± 0.08 (0.64, 0.76)	0.81 ± 0.04 (0.78, 0.84)	-0.11
	Lt. eye (2)	0.61 ± 0.12 (0.53, 0.69)	0.78 ± 0.06 (0.074, 0.81)	-0.17
	Mandible (2)	0.88 ± 0.07 (0.83, 0.93)	0.81 ± 0.06 (0.65, 0.76)	0.07

Breast	Heart (12)	0.93 ± 0.04 (0.90, 0.95)	0.71 ± 0.09 (0.65, 0.76)	0.22
	Rt. Lung (12)	0.98 ± 0.0 (0.98, 0.99)	0.96 ± 0.01 (0.96, 0.97)	0.02
	Lt. Lung (12)	0.97 ± 0.03 (0.95, 0.99)	0.96 ± 0.03 (0.95, 0.98)	0.01
Abdomen	Liver (3)	0.97	0.85	0.12
	Rt. Kidney (3)	0.91	0.50	0.41
	Lt. kidney (3)	0.89	0.88	0.01
Pelvis	Bladder (9)	0.72 ± 0.31 (0.45, 1.0)	0.52 ± 0.25 (0.31, 0.74)	0.20
	Rt. Femur head (9)	0.84 ± 0.13 (0.73, 0.95)	0.60 ± 0.12 (0.49, 0.71)	0.24
	Lt. Femur head (9)	0.81 ± 0.15 (0.68, 0.94)	0.56 ± 0.11 (0.46, 0.65)	0.25

- Table 10. 95% HD (mm) for each oragn by GE vendors

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (2)	3.37 ± 1.12 (2.60, 4.14)	4.01 ± 0.77 (3.48, 4.55)	-0.64
	Rt. Eye (2)	5.18 ± 1.16 (4.37, 5.98)	4.57 ± 1.37 (3.62, 5.52)	0.61
	Lt. eye (2)	5.63 ± 1.06 (4.89, 6.36)	6.27 ± 3.77 (3.66, 8.89)	-0.64
	Mandible (2)	2.64 ± 1.93 (1.30, 3.97)	64.50 ± 165.04 (16.94, 23.69)	-61.86
Breast	Heart (12)	8.00 ± 6.03 (4.43, 11.56)	20.31 ± 5.71 (16.94, 23.69)	-12.31
	Rt. Lung (12)	1.78 ± 0.66 (1.36, 2.19)	7.37 ± 2.43 (5.86, 8.88)	-5.59
	Lt. Lung (12)	9.56 ± 23.90 (-5.25, 24.37)	8.18 ± 10.41 (1.72, 14.63)	-1.38
Abdomen	Liver (3)	3.27	32.82	-29.55
	Rt. Kidney (3)	3.27	5.88	-2.61
	Lt. kidney (3)	3.27	6.55	-3.28
Pelvis	Bladder (9)	14.13 ± 11.93 (3.68, 24.59)	36.66 ± 31.09 (9.40, 63.91)	-22.53
	Rt. Femur head (9)	10.68 ± 9.53 (2.33, 19.04)	32.41 ± 12.58 (21.93, 43.44)	-21.73
	Lt. Femur head (9)	19.93 ± 22.34 (0.35, 39.51)	44.61 ± 11.01 (34.96, 54.26)	-24.68

- Table 11. DSC for each organ by PHILIPS vendors

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (11)	0.98 ± 0.01 (0.97, 0.98)	0.96 ± 0.01 (0.95, 0.96)	0.02
	Rt. Eye (11)	0.83 ± 0.09 (0.77, 0.88)	0.81 ± 0.07 (0.77, 0.86)	0.02
	Lt. eye (11)	0.74 ± 0.10 (0.69, 0.80)	0.76 ± 0.17 (0.67, 0.85)	0.02
	Mandible (11)	0.93 ± 0.03 (0.91, 0.94)	0.85 ± 0.06 (0.82, 0.89)	0.08
Breast	Heart	N/A	N/A	
	Rt. Lung	N/A	N/A	
	Lt. Lung	N/A	N/A	
Abdomen	Liver (6)	0.95 ± 0.02 (0.94, 0.97)	0.89 ± 0.08 (0.83, 0.95)	0.06
	Rt. Kidney (6)	0.88 ± 0.04 (0.85, 0.91)	0.67 ± 0.30 (0.43, 0.90)	0.21
	Lt. kidney (6)	0.87 ± 0.07 (0.81, 0.93)	0.75 ± 0.19 (0.59, 0.90)	0.12
Pelvis	Bladder (4)	0.88 ± 0.05 (0.83, 0.93)	0.31 ± 0.18 (0.14, 0.48)	0.57

	Rt. Femur head (4)	0.79 ± 0.16 (0.63, 0.94)	0.64 ± 0.15 (0.50, 0.79)	0.15
	Lt. Femur head (4)	0.77 ± 0.14 (0.63, 0.90)	0.63 ± 0.13 (0.50, 0.75)	0.14

- Table 12. 95% HD (mm) for each organ by PHILIPS vendors.

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (11)	2.57 ± 0.85 (2.07, 3.08)	5.30 ± 2.94 (3.56, 7.04)	-2.73
	Rt. Eye (11)	3.11 ± 1.31 (2.34, 3.88)	3.97 ± 1.43 (3.12, 4.81)	-0.86
	Lt. eye (11)	8.80 ± 16.77 (-1.10,18.71)	9.96 ± 16.13 (0.43, 19.49)	-1.16
	Mandible (11)	1.72 ± 0.67 (1.33, 2.12)	5.18 ± 5.27 (2.06, 8.29)	-3.46
Breast	Heart	N/A	N/A	
	Rt. Lung	N/A	N/A	
	Lt. Lung	N/A	N/A	
Abdom en	Liver (6)	4.18 ± 1.95 (2.62, 5.74)	18.06 ± 15.21 (5.89, 30.24)	-13.88
	Rt. Kidney (6)	4.54 ± 1.78 (3.12, 5.96)	17.55 ± 22.23 (-0.24, 35.34)	-13.01
	Lt. kidney (6)	6.30 ± 7.42 (0.36, 12.24)	11.38 ± 11.62 (2.07, 20.68)	-5.08
Pelvis	Bladder (4)	8.72 ± 5.85 (2.10, 15.34)	38.68 ± 8.49 (29.07, 48.29)	-29.96
	Rt. Femur head (4)	14.44 ± 18.68 (-6.70, 35.58)	24.39 ± 23.29 (-1.96, 50.75)	-9.95
	Lt. Femur head (4)	54.37 ± 59.01 (-12.40, 121.14)	37.60 ± 5.32 (31.58, 43.61)	16.77

- Table 13. DSC for each organ by TOSHIBA vendors

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (2)	0.96 ± 0.02 (0.93, 0.99)	0.95 ± 0.01 (0.94, 0.97)	0.01
	Rt. Eye (2)	0.86 ± 0.05 (0.78, 0.93)	0.75 ± 0.03 (0.71, 0.79)	0.11
	Lt. eye (2)	0.84 ± 0.06 (0.76, 0.93)	0.74 ± 0.03 (0.70, 0.77)	0.10
	Mandible (2)	0.94 ± 0.0 (0.93, 0.94)	0.85 ± 0.01 (0.84, 0.86)	0.09
Breast	Heart (12)	0.95 ± 0.02 (0.94, 0.96)	0.85 ± 0.09 (0.80, 0.90)	0.10
	Rt. Lung (12)	0.97 ± 0.01 (0.96, 0.98)	0.96 ± 0.02 (0.95, 0.97)	0.01
	Lt. Lung (12)	0.97 ± 0.01 (0.96, 0.98)	0.95 ± 0.04 (0.93, 0.98)	0.02
Abdom en	Liver (3)	0.95 ± 0.01 (0.94, 0.96)	0.92 ± 0.04 (0.87, 0.97)	0.03
	Rt. Kidney (3)	0.92 ± 0.02 (0.90, 0.94)	0.89 ± 0.04 (0.84, 0.94)	0.03
	Lt. kidney (3)	0.93 ± 0.03 (0.90, 0.96)	0.91 ± 0.04 (0.86, 0.96)	0.02
Pelvis	Bladder (9)	0.95 ± 0.02 (0.93, 0.96)	0.52 ± 0.26 (0.35, 0.69)	0.43
	Rt. Femur head (9)	0.85 ± 0.10 (0.78, 0.91)	0.56 ± 0.09 (0.50, 0.62)	0.29
	Lt. Femur head (9)	0.88 ± 0.07 (0.84, 0.92)	0.58 ± 0.08 (0.53, 0.63)	0.30

- Table 14. 95% HD (mm) for each organ by TOSHIBA vendors.

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (2)	2.53 ± 2.08 (-0.36, 5.41)	5.86 ± 1.89 (3.24, 8.48)	-3.33
	Rt. Eye (2)	2.62 ± 0.40 (2.06,3.18)	5.10 ± 0.26 (4.73, 5.46)	-2.48
	Lt. eye (2)	2.35 ± 0.79 (1.26, 3.44)	6.31 ± 0.44 (5.70, 6.93)	-3.96
	Mandible (2)	1.28 ± 0.31 (0.85, 1.71)	3.50 ± 0.57 (2.71, 4.28)	-2.22
Breast	Heart (12)	4.74 ± 2.22 (3.48, 5.99)	16.66 ± 5.07 (13.79, 19.53)	-11.92

	Rt. Lung (12)	3.93 ± 2.16 (2.71, 5.15)	6.54 ± 3.63 (4.48, 8.59)	-2.61
	Lt. Lung (12)	2.65 ± 0.62 (2.30, 3.00)	2.94 ± 0.55 (2.63, 3.25)	-0.29
Abdomen	Liver (3)	4.17 ± 1.36 (2.63, 5.74)	11.39 ± 11.38 (-1.48, 24.27)	-7.22
	Rt. Kidney (3)	4.30 ± 2.32 (1.68, 6.91)	6.81 ± 3.43 (2.94, 10.69)	-2.51
	Lt. kidney (3)	3.39 ± 1.05 (2.20, 4.47)	5.59 ± 3.12 (2.06, 9.12)	-2.2
Pelvis	Bladder (9)	3.80 ± 1.03 (3.13, 4.47)	36.27 ± 29.82 (16.79, 55.76)	-32.47
	Rt. Femur head (9)	12.40 ± 9.95 (5.90, 18.90)	42.77 ± 7.46 (37.89, 47.64)	-30.37
	Lt. Femur head (9)	11.57 ± 10.16 (4.94, 18.21)	42.54 ± 6.74 (38.13, 46.94)	-30.37

- Table 15. DSC for each organ by ≥1, ≤2 slice thickness

Part	Organ	AVIEW	Predicate device	Difference
Head&Neck	Brain (9)	0.97 ± 0.01 (0.96, 0.98)	0.96 ± 0.01 (0.95, 0.96)	0.01
	Rt. Eye (9)	0.86 ± 0.07 (0.78, 0.87)	0.80 ± 0.06 (0.76, 0.84)	0.06
	Lt. eye (9)	0.79 ± 0.08 (0.74, 0.84)	0.80 ± 0.06 (0.76, 0.84)	-0.01
	Mandible (9)	0.91 ± 0.03 (0.89, 0.93)	0.81 ± 0.09 (0.75, 0.87)	0.1
Breast	Heart (1)	0.93	0.69	0.24
	Rt. Lung (1)	0.98	0.97	0.01
	Lt. Lung (1)	0.97	0.97	0.00
Abdomen	Liver (5)	0.97 ± 0.01 (0.95, 0.98)	0.88 ± 0.02 (0.86, 0.91)	0.09
	Rt. Kidney (5)	0.90 ± 0.01 (0.87, 0.93)	0.76 ± 0.17 (0.61, 0.91)	0.14
	Lt. kidney (5)	0.88 ± 0.08 (0.80, 0.95)	0.86 ± 0.08 (0.79, 0.93)	0.02
Pelvis	Bladder (3)	0.88 ± 0.06 (0.81, 0.95)	0.05 ± 0.24 (0.24, 0.77)	0.38
	Rt. Femur head (3)	0.76 ± 0.10 (0.88, 0.65)	0.71 ± 0.08 (0.59, 0.82)	0.05
	Lt. Femur head (3)	0.71 ± 0.02 (0.69, 0.74)	0.72 ± 0.03 (0.68, 0.75)	-0.01

- Table 16. 95% HD (mm) for each organ by ≥1, ≤2 slice thickness

Part	Organ	AVIEW	Predicate device	Difference
Head&Neck	Brain (9)	14.24 ± 34.04 (-8.0, 36.48)	4.48 ± 1.39 (3.55, 5.36)	9.76
	Rt. Eye (9)	3.15 ± 1.06 (2.46, 3.84)	4.23 ± 1.32 (3.37, 5.09)	-1.08
	Lt. eye (9)	3.58 ± 1.60 (2.54, 4.63)	5.57 ± 3.64 (3.29, 8.04)	-1.99
	Mandible (9)	1.93 ± 0.60 (1.53, 2.32)	6.06 ± 5.98 (2.15, 9.97)	-4.13
Breast	Heart (1)	8	15.93	-7.93
	Rt. Lung (1)	2	5.33	-3.33
	Lt. Lung (1)	2	2.18	-0.18
Abdomen	Liver (5)	14.72 ± 25.47 (-7.61, 37.05)	30.88 ± 19.29 (13.97, 47.79)	-16.16
	Rt. Kidney (5)	13.10 ± 17.17 (-1.95, 28.15)	18.69 ± 15.09 (5.46, 31.91)	-5.59
	Lt. kidney (5)	7.50 ± 7.90 (0.58, 14.42)	13.08 ± 9.35 (4.88, 21.27)	-5.58
Pelvis	Bladder (3)	10.11 ± 6.48 (1.13, 19.09)	33.06 ± 9.55 (46.29, 19.82)	-22.95
	Rt. Femur head (3)	16.16 ± 16.74 (-7.04, 39.36)	16.27 ± 21.85 (-14.01, 46.56)	-0.11
	Lt. Femur head (3)	73.29 ± 64.05 (-15.48, 162.06)	34.0 ± 8.21 (22.62, 45.38)	39.29

- Table 17. DSC for each organ by >2, ≤3 slice thickness

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (9)	0.98 ± 0.01 (0.97, 0.98)	0.96 ± 0.01 (0.95, 0.96)	0.02
	Rt. Eye (9)	0.84 ± 0.08 (0.79, 0.90)	0.79 ± 0.08 (0.74, 0.84)	0.05
	Lt. eye (9)	0.74 ± 0.1 (0.67, 0.80)	0.72 ± 0.18 (0.61, 0.84)	0.02
	Mandible (9)	0.94 ± 0.03 (0.92, 0.96)	0.88 ± 0.03 (0.85, 0.90)	0.06
Breast	Heart (20)	0.95 ± 0.02 (0.94, 0.96)	0.81 ± 0.10 (0.77, 0.86)	0.14
	Rt. Lung (20)	0.97 ± 0.01 (0.97, 0.98)	0.96 ± 0.02 (0.95, 0.97)	0.01
	Lt. Lung (20)	0.97 ± 0.02 (0.96, 0.97)	0.95 ± 0.03 (0.94, 0.97)	0.02
Abdom en	Liver (15)	0.96 ± 0.01 (0.95, 0.96)	0.88 ± 0.07 (0.84, 0.92)	0.08
	Rt. Kidney (15)	0.90 ± 0.02 (0.89, 0.92)	0.75 ± 0.02 (0.65, 0.85)	0.15
	Lt. kidney (15)	0.91 ± 0.04 (0.89, 0.92)	0.78 ± 0.13 (0.71, 0.85)	0.13
Pelvis	Bladder (24)	0.89 ± 0.16 (0.83, 0.95)	0.48 ± 0.28 (0.37, 0.59)	0.41
	Rt. Femur head (24)	0.88 ± 0.09 (0.84, 0.91)	0.57 ± 0.10 (0.53, 0.61)	0.31
	Lt. Femur head (24)	0.88 ± 0.09 (0.84, 0.91)	0.54 ± 0.12 (0.50, 0.59)	0.34

- Table 18. 95% HD (mm) for each organ by >2, ≤3 slice thickness

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (9)	2.29 ± 0.67 (1.85, 2.73)	5.28 ± 3.29 (3.13, 7.43)	-2.99
	Rt. Eye (9)	2.91 ± 1.12 (2.18, 3.64)	4.56 ± 1.58 (3.53, 5.60)	-1.65
	Lt. eye (9)	9.77 ± 18.56 (-2.35, 21.9)	11.80 ± 17.47 (0.38, 23.21)	-2.03
	Mandible (9)	1.45 ± 0.51 (1.11, 1.79)	3.71 ± 1.71 (2.59, 4.82)	-2.26
Breast	Heart (20)	5.11 ± 2.56 (3.99, 6.23)	18.12 ± 4.84 (16.0, 20.24)	-13.01
	Rt. Lung (20)	3.48 ± 1.77 (2.71, 4.26)	6.94 ± 3.25 (5.52, 8.67)	-3.46
	Lt. Lung (20)	2.83 ± 0.50 (2.61, 3.04)	3.29 ± 0.95 (2.87, 3.70)	-0.46
Abdom en	Liver (15)	3.99 ± 1.51 (3.22, 4.75)	20.99 ± 16.1 (12.85, 29.14)	-17
	Rt. Kidney (15)	3.99 ± 1.16 (3.40, 4.57)	13.43 ± 14.1 (6.32, 20.55)	-9.44
	Lt. kidney (15)	4.35 ± 2.85 (2.91, 5.79)	14.46 ± 10.63 (9.08, 19.83)	-10.11
Pelvis	Bladder (24)	6.81 ± 8.68 (3.34, 10.29)	30.16 ± 24.80 (20.02, 40.30)	-23.35
	Rt. Femur head (24)	10.01 ± 8.79 (6.63, 13.39)	41.54 ± 8.85 (38.07, 45.01)	-31.53
	Lt. Femur head (24)	10.51 ± 9.74 (6.76, 14.25)	41.95 ± 8.57 (38.59, 45.31)	-31.44

- Table 19. DSC for each oragan. by >3, ≤4 slice thickness

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (7)	0.96 ± 0.01 (0.96, 0.97)	0.96 ± 0.00 (0.96, 0.97)	0.00
	Rt. Eye (7)	0.68 ± 0.07 (0.63, 0.74)	0.81 ± 0.05 (0.78, 0.85)	-0.13
	Lt. eye (7)	0.59 ± 0.1 (0.51, 0.66)	0.78 ± 0.06 (0.74, 0.82)	-0.19
	Mandible (7)	0.87 ± 0.07 (0.82, 0.92)	0.80 ± 0.06 (0.76, 0.84)	0.07
Breast	Heart (10)	0.94 ± 0.02 (0.93, 0.95)	0.70 ± 0.09 (0.64, 0.75)	0.24
	Rt. Lung (10)	0.98 ± 0.0 (0.98, 0.99)	0.96 ± 0.01 (0.96, 0.97)	0.02
	Lt. Lung (10)	0.97 ± 0.03 (0.95, 0.99)	0.96 ± 0.03 (0.95, 0.98)	0.01
Abdom	Liver (1)	0.97 ± 0.01 (0.95, 0.98)	0.92	0.05

en	Rt. Kidney (1)	0.90 ± 0.01 (0.87, 0.93)	0.89	0.01
	Lt. kidney (1)	0.88 ± 0.08 (0.80, 0.95)	0.88	0.00
Pelvis	Bladder (2)	0.88 ± 0.06 (0.81, 0.95)	0.37 ± 0.17 (0.13, 0.60)	0.51
	Rt. Femur head (2)	0.76 ± 0.10 (0.88, 0.65)	0.63 ± 0.24 (0.29, 0.96)	0.13
	Lt. Femur head (2)	0.71 ± 0.02 (0.69, 0.74)	0.52 ± 0.19 (0.26, 0.79)	0.19

- Table 20. 95% HD (mm) for each oragan. By >3, ≤4 slice thickness

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (7)	3.45 ± 1.18 (2.58, 4.33)	3.94 ± 0.80 (3.35, 4.54)	-0.49
	Rt. Eye (7)	5.35 ± 1.15 (4.5, 6.2)	4.32 ± 1.27 (3.38, 5.27)	1.03
	Lt. eye (7)	5.63 ± 1.15 (4.78, 6.48)	5.2 ± 2.41 (3.41, 6.98)	0.43
	Mandible (7)	2.83 ± 2.0 (1.36, 4.31)	73.16 ± 176.29 (-57.43, 203.76)	-70.33
Breast	Heart (10)	8.13 ± 6.34 (4.2, 12.06)	19.84 ± 5.79 (16.25, 23.43)	-11.71
	Rt. Lung (10)	1.61 ± 0.43 (1.33, 1.89)	7.37 ± 2.43 (5.86, 8.88)	-5.76
	Lt. Lung (10)	10.26 ± 25.24 (-6.23, 26.75)	8.18 ± 10.41 (1.72, 14.63)	2.08
Abdomen	Liver (1)	3.27	32.82	-29.55
	Rt. Kidney (1)	3.27	5.88	-2.61
	Lt. kidney (1)	3.27	6.55	-3.28
Pelvis	Bladder (2)	18.16 ± 14.90 (-2.49, 38.81)	68.99 ± 15.60 (47.37, 90.61)	-50.83
	Rt. Femur head (2)	14.21 ± 10.85 (-0.82, 29.24)	19.92 ± 4.20 (14.11, 25.74)	-5.71
	Lt. Femur head (2)	32.33 ± 36.47 (-18.22, 82.87)	50.32 ± 16.58 (27.34, 73.29)	-17.99

- Table 21. DSC for each oragan. by >4, ≤5slice thickness

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain	N/A	N/A	
	Rt. Eye	N/A	N/A	
	Lt. eye	N/A	N/A	
	Mandible	N/A	N/A	
Breast	Heart (1)	0.82	0.81	0.01
	Rt. Lung	N/A	N/A	
	Lt. Lung	N/A	N/A	
Abdomen	Liver (5)	0.96 ± 0.0 (0.96, 0.97)	0.84 ± 0.04 (0.81, 0.87)	0.12
	Rt. Kidney (5)	0.91 ± 0.02 (0.89, 0.92)	0.72 ± 0.16 (0.57, 0.86)	0.19
	Lt. kidney (5)	0.91 ± 0.01 (0.89, 0.92)	0.74 ± 0.08 (0.67, 0.81)	0.17
Pelvis	Bladder (6)	0.91 ± 0.09 (0.84, 0.98)	0.69 ± 0.12 (0.59, 0.78)	0.22
	Rt. Femur head (6)	0.90 ± 0.06 (0.85, 0.95)	0.55 ± 0.06 (0.50, 0.60)	0.35
	Lt. Femur head (6)	0.90 ± 0.05 (0.86, 0.95)	0.55 ± 0.05 (0.51, 0.59)	0.35

- Table 22. 95% HD (mm) for each oragan. by >4, ≤5 slice thickness

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain	N/A	N/A	
	Rt. Eye	N/A	N/A	
	Lt. eye	N/A	N/A	
	Mandible	N/A	N/A	
Breast	Heart (1)	6.68	25	-18.32
	Rt. Lung	N/A	N/A	
	Lt. Lung	N/A	N/A	
Abdomen	Liver (5)	9.97 ± 11.42 (-0.04, 19.98)	27.57 ± 5.71 (22.57, 32.58)	-17.6
	Rt. Kidney (5)	9.86 ± 11.31 (-0.05, 19.77)	15.91 ± 10.03 (7.12, 24.70)	6.05
	Lt. kidney (5)	6.56 ± 3.48 (3.51, 9.60)	21.18 ± 12.75 (10.0, 32.36)	-14.62
Pelvis	Bladder (6)	5.1 ± 3.86 (2.01, 8.19)	19.33 ± 6.58 (14.06, 24.60)	-14.23
	Rt. Femur head (6)	9.07 ± 8.89 (1.96, 16.19)	42.35 ± 5.09 (38.28, 46.42)	-33.28
	Lt. Femur head (6)	8.71 ± 9.21 (1.35, 16.08)	42.84 ± 4.11 (36.55, 46.13)	-34.13

- Table 23. DSC for each oragan. By soft kernel

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (12)	0.97 ± 0.01 (0.96, 0.98)	0.96 ± 0.01 (0.95, 0.96)	0.01
	Rt. Eye (12)	0.82 ± 0.09 (0.77, 0.88)	0.78 ± 0.06 (0.75, 0.82)	0.04
	Lt. eye (12)	0.73 ± 0.14 (0.65, 0.81)	0.73 ± 0.15 (0.64, 0.81)	0.00
	Mandible (12)	0.92 ± 0.05 (0.89, 0.95)	0.85 ± 0.06 (0.82, 0.89)	0.07
Breast	Heart (17)	0.95 ± 0.02 (0.94, 0.95)	0.80 ± 0.12 (0.75, 0.86)	0.15
	Rt. Lung (17)	0.98 ± 0.01 (0.97, 0.98)	0.96 ± 0.01 (0.96, 0.97)	0.02
	Lt. Lung (17)	0.97 ± 0.01 (0.97, 0.98)	0.96 ± 0.03 (0.94, 0.97)	0.01
Abdomen	Liver (4)	0.96 ± 0.01 (0.94, 0.97)	0.88 ± 0.08 (0.80, 0.96)	0.08
	Rt. Kidney (4)	0.92 ± 0.02 (0.91, 0.94)	0.80 ± 0.17 (0.64, 0.97)	0.12
	Lt. kidney (4)	0.93 ± 0.02 (0.91, 0.96)	0.85 ± 0.12 (0.73, 0.97)	0.08
Pelvis	Bladder (15)	0.91 ± 0.08 (0.87, 0.95)	0.47 ± 0.25 (0.34, 0.59)	0.44
	Rt. Femur head (14)	0.83 ± 0.11 (0.77, 0.89)	0.61 ± 0.12 (0.55, 0.67)	0.22
	Lt. Femur head (14)	0.84 ± 0.10 (0.79, 0.89)	0.58 ± 0.09 (0.53, 0.63)	0.26

- Table 24. 95% HD (mm) for each oragan. By soft kernel

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (12)	2.84 ± 1.40 (2.05, 3.63)	5.44 ± 2.87 (3.82, 7.07)	-2.60
	Rt. Eye (12)	3.29 ± 1.50 (2.44, 4.14)	4.58 ± 1.21 (3.89, 5.26)	-1.29
	Lt. eye (12)	8.28 ± 16.10 (-0.83, 17.39)	10.15 ± 15.15 (1.58, 18.72)	-1.87
	Mandible (12)	1.96 ± 1.72 (0.98, 2.93)	4.28 ± 3.05 (2.56, 6.00)	-2.32
Breast	Heart (17)	6.43 ± 5.29 (3.91, 8.94)	18.13 ± 5.42 (15.56, 20.71)	-11.70
	Rt. Lung (17)	3.34 ± 2.14 (2.29, 4.39)	6.53 ± 3.20 (4.96, 8.10)	-3.19
	Lt. Lung (17)	2.45 ± 0.76 (2.07, 2.82)	3.05 ± 0.57 (2.77, 3.33)	-0.60
Abdom	Liver (4)	3.75 ± 1. 40 (2.38, 5.12)	18.46 ± 16.92 (1.88, 35.04)	-14.71

en	Rt. Kidney (4)	3.88 ± 2.06 (1.86, 5.90)	6.61 ± 2.83 (3.84, 9.38)	-2.73
	Lt. kidney (4)	3.17 ± 0.97 (2.21, 4.12)	5.86 ± 2.60 (3.31, 8.40)	-2.69
Pelvis	Bladder (15)	14.83 ± 30.69 (-1.24, 30.91)	38.59 ± 24.31 (25.85, 51.33)	-23.76
	Rt. Femur head (14)	12.42 ± 11.32 (6.27, 18.57)	36.54 ± 15.01 (28.38, 44.70)	-24.12
	Lt. Femur head (14)	12.94 ± 12.92 (5.62, 20.25)	41.20 ± 6.61 (37.46, 44.94)	-28.26

- Table 25. DSC for each oragan. By standard kernel

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (4)	0.97 ± 0.01 (0.96, 0.98)	0.96 ± 0.00 (0.96, 0.97)	0.01
	Rt. Eye (4)	0.67 ± 0.11 (0.57, 0.77)	0.79 ± 0.03 (0.76, 0.81)	-0.12
	Lt. eye (4)	0.62 ± 0.13 (0.49, 0.74)	0.76 ± 0.04 (0.73, 0.80)	-0.14
	Mandible (4)	0.92 ± 0.04 (0.88, 0.96)	0.82 ± 0.03 (0.79, 0.85)	0.10
Breast	Heart (6)	0.92 ± 0.05 (0.88, 0.96)	0.70 ± 0.07 (0.64, 0.76)	0.22
	Rt. Lung (6)	0.99 ± 0.00 (0.98, 0.99)	0.96 ± 0.01 (0.95, 0.97)	0.03
	Lt. Lung (6)	0.96 ± 0.05 (0.92, 1.00)	0.95 ± 0.03 (0.92, 0.98)	0.01
Abdomen	Liver (1)	0.97	0.85	0.12
	Rt. Kidney (1)	0.91	0.50	0.41
	Lt. kidney (1)	0.89	0.88	0.01
Pelvis	Bladder (4)	0.73 ± 0.36 (0.38, 1.09)	0.59 ± 0.22 (0.37, 0.81)	0.14
	Rt. Femur head (4)	0.84 ± 0.14 (0.70, 0.99)	0.56 ± 0.07 (0.49, 0.63)	0.28
	Lt. Femur head (4)	0.81 ± 0.17 (0.64, 0.98)	0.53 ± 0.11 (0.43, 0.63)	0.28

- Table 26. 95% HD (mm) for each oragan. By standard kernel

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (4)	2.82 ± 0.63 (2.21, 3.44)	3.96 ± 0.54 (3.43, 4.48)	-1.14
	Rt. Eye (4)	5.48 ± 1.25 (4.26, 6.70)	5.06 ± 1.62 (3.47, 6.65)	0.42
	Lt. eye (4)	5.77 ± 1.19 (4.60, 6.94)	7.67 ± 5.05 (2.72, 12.62)	1.90
	Mandible (4)	1.90 ± 0.83 (1.09, 2.71)	5.14 ± 3.19 (2.01, 8.26)	-3.24
Breast	Heart (6)	5.93 ± 2.43 (3.99, 7.87)	19.18 ± 6.49 (13.99, 24.38)	-13.25
	Rt. Lung (6)	1.91 ± 0.78 (1.29, 2.53)	7.94 ± 2.82 (5.68, 10.20)	-6.03
	Lt. Lung (6)	14.70 ± 30.79 (-9.94, 39.34)	11.38 ± 12.80 (1.14, 21.63)	3.32
Abdomen	Liver (1)	3.27	32.82	-29.55
	Rt. Kidney (1)	3.27	5.88	-2.61
	Lt. kidney (1)	3.27	6.55	-3.28
Pelvis	Bladder (4)	10.49 ± 10.06 (0.63, 20.36)	31.33 ± 33.16 (-1.17, 63.83)	-20.84
	Rt. Femur head (4)	11.72 ± 10.67 (1.26, 22.18)	36.28 ± 10.56 (25.93, 46.62)	-24.56
	Lt. Femur head (4)	23.28 ± 24.30 (-0.54, 47.10)	46.11 ± 12.11 (34.24, 57.98)	-22.83

- Table 27. DSC for each oragan. By medium kernel

Part	Organ	AVIEW	Predicate device	Difference
Head&	Brain (4)	0.97 ± 0.01 (0.97, 0.98)	0.96 ± 0.00 (0.96, 0.97)	0.01

Neck	Rt. Eye (4)	0.85 ± 0.05 (0.80, 0.90)	0.77 ± 0.05 (0.72, 0.82)	0.08
	Lt. eye (4)	0.78 ± 0.08 (0.71, 0.86)	0.77 ± 0.05 (0.72, 0.82)	0.01
	Mandible (4)	0.91 ± 0.04 (0.87, 0.94)	0.81 ± 0.13 (0.68, 0.94)	0.10
Breast	Heart (9)	0.94 ± 0.02 (0.93, 0.96)	0.75 ± 0.10 (0.69, 0.82)	0.19
	Rt. Lung (9)	0.97 ± 0.01 (0.96, 0.98)	0.95 ± 0.02 (0.94, 0.97)	0.02
	Lt. Lung (9)	0.96 ± 0.02 (0.95, 0.97)	0.95 ± 0.02 (0.94, 0.97)	0.01
Abdomen	Liver (16)	0.96 ± 0.01 (0.96, 0.97)	0.86 ± 0.06 (0.84, 0.89)	0.10
	Rt. Kidney (16)	0.91 ± 0.02 (0.90, 0.92)	0.77 ± 0.12 (0.72, 0.83)	0.14
	Lt. kidney (16)	0.91 ± 0.03 (0.89, 0.92)	0.78 ± 0.08 (0.74, 0.82)	0.13
Pelvis	Bladder (17)	0.90 ± 0.07 (0.87, 0.93)	0.55 ± 0.27 (0.42, 0.67)	0.35
	Rt. Femur head (19)	0.90 ± 0.06 (0.87, 0.93)	0.56 ± 0.10 (0.51, 0.61)	0.34
	Lt. Femur head (19)	0.89 ± 0.09 (0.85, 0.93)	0.53 ± 0.13 (0.47, 0.58)	0.36

- Table 28. 95% HD (mm) for each oragan. By medium kernel

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (4)	28.16 ± 51.23 (-22.04, 78.36)	3.28 ± 0.45 (2.84, 3.72)	24.88
	Rt. Eye (4)	2.77 ± 0.37 (2.42, 3.13)	4.75 ± 1.50 (3.29, 6.22)	-1.98
	Lt. eye (4)	3.26 ± 0.53 (2.74, 3.78)	5.30 ± 2.18 (3.16, 7.44)	-2.04
	Mandible (4)	1.91 ± 0.51 (1.42, 2.41)	5.04 ± 4.11 (1.01, 9.08)	-3.13
Breast	Heart (9)	5.92 ± 2.97 (3.98, 7.86)	20.17 ± 3.52 (17.86, 22.47)	-14.25
	Rt. Lung (9)	2.73 ± 0.61 (2.33, 3.13)	7.30 ± 2.63 (5.58, 9.02)	-4.57
	Lt. Lung (9)	2.97 ± 0.26 (2.80, 3.14)	3.63 ± 1.25 (2.81, 4.45)	-0.66
Abdomen	Liver (16)	9.10 ± 15.19 (1.66, 16.55)	29.04 ± 14.54 (21.92, 36.16)	-19.94
	Rt. Kidney (16)	8.40 ± 11.42 (2.81, 14.00)	15.54 ± 9.83 (10.73, 20.36)	-7.14
	Lt. kidney (16)	5.47 ± 3.29 (3.86, 7.08)	18.94 ± 10.02 (14.03, 23.85)	-13.47
Pelvis	Bladder (17)	7.04 ± 9.22 (2.65, 11.42)	23.99 ± 17.93 (15.71, 32.27)	-16.95
	Rt. Femur head (19)	8.01 ± 6.47 (5.10, 10.92)	50.42 ± 39.59 (32.13, 38.71)	-42.41
	Lt. Femur head (19)	8.57 ± 7.05 (5.40, 11.74)	41.98 ± 9.27 (37.7, 46.27)	-33.41

- Table 29. DSC for each oragan. By sharp kernel

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (5)	0.97 ± 0.01 (0.96, 0.98)	0.96 ± 0.01 (0.96, 0.97)	0.01
	Rt. Eye (5)	0.77 ± 0.07 (0.70, 0.83)	0.87 ± 0.04 (0.84, 0.91)	-0.10
	Lt. eye (5)	0.71 ± 0.07 (0.65, 0.77)	0.85 ± 0.05 (0.81, 0.90)	-0.14
	Mandible (5)	0.88 ± 0.06 (0.83, 0.93)	0.80 ± 0.07 (0.74, 0.86)	0.08
Breast	Heart	N/A	N/A	
	Rt. Lung	N/A	N/A	
	Lt. Lung	N/A	N/A	
Abdomen	Liver (5)	0.95 ± 0.02 (0.93, 0.96)	0.91 ± 0.06 (0.86, 0.96)	0.04
	Rt. Kidney (5)	0.87 ± 0.03 (0.84, 0.90)	0.69 ± 0.32 (0.40, 0.97)	0.18
	Lt. kidney (5)	0.86 ± 0.07 (0.79, 0.92)	0.76 ± 0.21 (0.58, 0.95)	0.10
Pelvis	Bladder	N/A	N/A	
	Rt. Femur head	N/A	N/A	
	Lt. Femur	N/A	N/A	

	head			

- Table 30. 95% HD (mm) for each oragan. By sharp kernel

Part	Organ	AVIEW	Predicate device	Difference
Head& Neck	Brain (5)	3.00 ± 0.42 (2.64, 3.37)	4.20 ± 0.87 (3.44, 4.96)	-1.20
	Rt. Eye (5)	3.90 ± 1.24 (2.81, 4.99)	3.05 ± 0.68 (2.45, 3.65)	0.85
	Lt. eye (5)	4.83 ± 1.50 (3.52, 6.14)	3.97 ± 2.85 (1.47, 6.47)	-0.86
	Mandible (5)	2.30 ± 0.41 (1.94, 2.66)	101.61 ± 207.65 (-80.40, 283.61)	-99.31
Breast	Heart	N/A	N/A	
	Rt. Lung	N/A	N/A	
	Lt. Lung	N/A	N/A	
Abdomen	Liver (5)	4.52 ± 1.97 (2.79, 6.25)	13.74 ± 12.22 (3.03, 24.45)	-9.22
	Rt. Kidney (5)	4.92 ± 1.69 (3.44, 6.40)	19.86 ± 24.04 (-1.21, 40.93)	-14.94
	Lt. kidney (5)	7.06 ± 8.03 (0.02. 14.20)	12.32 ± 12.74 (1.16, 23.48)	-5.26
Pelvis	Bladder	N/A	N/A	
	Rt. Femur head	N/A	N/A	
	Lt. Femur head	N/A	N/A	

* There are organs that aren' available in a certain range or vendor which the value was input as N/A

◆ Number of samples for each analysis

Table 31.

each part	Head & Neck	Breast	Abdomen	Pelvis	Total
N	25	32	26	27	120
Each part by organs	Head & Neck	Breast	Abdomen	Pelvis	Total
N	100	94	78	109	
Each vendor	SIEMENS	GE	PHILIPS	TOSHIBA	Total
N	48	25	21	26	120
each slice thickness (mm)	≥1, ≤2	>2, ≤3	>3, ≤4	>4, ≤5	Total
N	18	70	20	12	120
Each kernel	SOFT	STANDARD	MEDIUM	SHARP	Total
N	47	15	48	20	120

10 CONCLUSIONS

The new device and predicate device are substantially equivalent in the areas of technical characteristics, general functions, application, and intended use. The new device does not introduce a fundamentally new scientific technology, and the nonclinical tests demonstrate that the device is as safe and as effective as the predicate. Therefore, it is our opinion that the AVIEW RT ACS described in this submission is substantially equivalent to the predicate device.