January 23, 2026

Manteia Technologies Co., Ltd.
Chao Fang
Quality Manager
Unit 3001-3005
No.5 Huizhan North Road
Xiamen, Fujian 361008
China

Re: K251351
Trade/Device Name: AccuContour 4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: April 30, 2025
Received: April 30, 2025

Dear Chao Fang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
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)*
K251351

Device Name
AccuContour 4.0

Indications for Use *(Describe)*
It is used by radiation oncology department to segment CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaption.

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

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

The assign 510(k) Number: K251351

## I. SUBMITTER

Manteia Technologies Co., Ltd.
Unit 3001-3005, No.5 Huizhan North Road, Xiamen, Fujian, P.R. China
Establishment Registration Number: 3016686005
Contact Person: Chao Fang
Position: Quality Manager
Email: ra@manteiatech.com
Date of Prepared: 12/18/2025

## II. DEVICE

Name of Device: AccuContour 4.0
Common or Usual Name: AI-assisted Auto-contouring Tool
Classification Name: Radiological Image Processing Software For Radiation Therapy
Regulatory Class: Class II
Product Code: QKB

## III. PREDICATE DEVICE

Predicate Device: AccuContour, K221706

## IV. DEVICE DESCRIPTION

The proposed device, AccuContour 4.0 Family, is a standalone software with the following variants: AccuContour and AccuContour-Lite. The functions of AccuContour-Lite is a subset of AccuContour.

**AccuContour:**
It is used by oncology department to register multi-modality images and segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation.
The product has two image processing functions:
(1) Deep learning contouring: it can automatically contour organs-at-risk, in head and neck, thorax, abdomen and pelvis (for both male and female) areas,
(2) Automatic registration: rigid and deformable registration, and
(3) Manual contouring.

It also has the following general functions:
Receive, add/edit/delete, transmit, input/export, medical images and DICOM data;
Patient management;
Review tool of processed images;
Extension tool;
Plan evaluation and plan comparison;
Dose analysis.

**AccuContour-Lite:**
It is used by oncology department to segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation.
The product has one image processing function:
Deep learning contouring: it can automatically contour organs-at-risk, in head and neck, thorax, abdomen and pelvis (for both male and female) areas,
It also has the following general functions:
Receive, add/edit/delete, transmit, input/export, medical images and DICOM data;
Patient management;
Review tool of processed images.

## V. INDICATIONS FOR USE

It is used by radiation oncology department to segment CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaption.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The major changes in the subject device compared with the predicate device are as follow:
- Added the AccuContour-Lite variant as a lightweight version of AccuContour
- Added AI-based Synthetic CT auto-contouring CT including 46 organs & structures
- Added registration support for 4DCT

The detailed comparison of technical parameters is shown in the table below.

| **ITEM** | **Subject Device AccuContour 4.0** | | **Predicate Device AccuContour (K221706)** |
|---|---|---|---|
| **Device Name** | **AccuContour** | **AccuContour-Lite** | **AccuContour** |
| Regulatory Information | | | |
| Regulation No. | 21 CFR 892.2050 | | 21 CFR 892.2050 |
| Product Code | QKB | | QKB |
| Class | II | | II |
| Intended Use | It is used by radiation oncology department to segment CT images, to generate needed information for treatment planning, treatment evaluation and | | It is used by radiation oncology department to register multi-modality |

| | | | |
|---|---|---|---|
| | treatment adaptation. | | images and segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation. |
| Intended User | Clinically qualified radiotherapy personnel with training. | | Clinically qualified radiotherapy personnel with training. |
| Independent Software | Yes | | Yes |
| Technological Characteristics | | | |
| Operating System | Windows | Windows | Windows |
| Top Toolbar | Yes | Yes | Yes |
| Patient Management | Yes | Yes | Yes |
| Contour | Yes | Yes | Yes |
| Fusion Registration | Yes | No | Yes |
| Plan Comparison | Yes | No | Yes |
| Dose Display | Yes | No | Yes |
| Patient Management Features | | | |
| Receive Files | Yes | Yes | Yes |
| Import/Export | Yes | Yes | Yes |
| Search | Yes | Yes | Yes |
| Advanced Search | Yes | Yes | Yes |
| Refresh | Yes | Yes | Yes |
| Auto-contouring | Yes | Yes | Yes |
| Generate Images | Yes | No | Yes |
| Generate Projections | Yes | Yes | Yes |
| Contouring Features | | | |
| Algorithm | Deep learning with GPU/CPU support | Deep learning with GPU/CPU support | Deep learning with GPU support |
| Compatible Modality | Non-Contrast CT DICOM 3.0 compliance required.（Original CT and Synthetic CT） | Non-Contrast CT DICOM 3.0 compliance required.（Original CT and Synthetic CT） | Non-Contrast CT DICOM 3.0 compliance required.（Original CT） |
| Compatible Scanner Models | No limitation on scanner model, DICOM 3.0 compliance required. | No limitation on scanner model, DICOM 3.0 compliance required. | No limitation on scanner model, DICOM 3.0 compliance required. |
| Compatible Treatment Planning System | No limitation on scanner model, DICOM 3.0 compliance required. | No limitation on scanner model, DICOM 3.0 compliance required. | No limitation on scanner model, DICOM 3.0 compliance required. |
| Fusion Registration Features | | | |
| Algorithm | Intensity Based with | No | Intensity Based with GPU |

| | | | |
|---|---|---|---|
| | GPU/CPU support | | support |
| Registration Type | Rigid Registration, Deformable Registration | No | Rigid Registration, Deformable Registration |
| Compatible Modality | Auto rigid registration: CT, MRI, PET, 4DCT<br>Auto deformable registration: CT, MRI, CBCT, 4DCT | No | Auto rigid registration: CT, MRI, PET<br>Auto deformable registration: CT, MRI, CBCT |
| Compatible Scanner Models | No limitation on scanner model, DICOM 3.0 compliance required. | No | No limitation on scanner model, DICOM 3.0 compliance required. |
| Compatible Treatment Planning System | No limitation on scanner model, DICOM 3.0 compliance required. | No | No limitation on scanner model, DICOM 3.0 compliance required. |
| Registration Export | Yes | No | Yes |
| Fusion Contouring | Yes | No | Yes |
| Synchronized Contouring | Yes | No | Yes |
| Plan Comparison Feature | | | |
| Plan Evaluation | Yes | No | Yes |
| Plan Comparison | Yes | No | Yes |
| Export Report | Yes | No | Yes |
| Isodose Line Display | Yes | No | Yes |
| Dose Display Feature | | | |
| Dose Analysis | Yes | No | Yes |
| Dose to Contour | Yes | No | Yes |
| Dose Accumulation | Yes | No | Yes |
| ART Dose Accumulation | Yes | No | Yes |

## VII. PERFORMANCE DATA

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

### Biocompatibility Testing

Not Applicable (Standalone Software).

### Electrical Safety and Electromagnetic Compatibility (EMC)

Not Applicable (Standalone Software).

### Software Verification and Validation Testing

Software verification and validation testings were conducted, and documentation was

provided as recommended by *FDA's Guideline for Industry and FDA Staff - Content of Premarket Submission for Device Software Functions.* Verification and validation of the software was conducted to ensure that the product meet users needs and intended use. AccuContour passed all software verification and validation tests.

*Performance Test Report on Synthetic CT (sCT) Contouring Function*

The performance test was performed to evaluate the synthetic CT(sCT) auto-contouring function of the test article(AccuContour) by DICE and HD95 Assessment Method.Verify whether all ROI indicators meet the criteria by calculating the Dice Similarity Coefficient (DSC) and 95% Hausdorff Distance (HD95) between the automatically delineated contours and the gold-standard contours.Meanwhile, clinical experts evaluate the clinical applicability of the automatically delineated contours using a 1-5 scale scoring system.The results indicate that the auto-segmentation performance of the AccuContour system for sCT images derived from both CBCT and MR modalities meets the requirements for geometric accuracy.The average ratings of 4.4(for sCT generated from MR) and 4.5(for sCT generated from CBCT) were found across all structure models demonstrating that only minor edits would be required in order to make the structure models acceptable for clinical use. The test results are presented in Table 1 and Table 2.

A total of 247 synthetic CT images were used in the test, comprising 116 generated from MR and 131 generated from CBCT. The test data set information is as follows:

(1) In terms of demographic distribution, the sample consisted of 57% male and 43% female patients. With reference to the 2020 U.S. Census adult gender ratio (approximately 1:1) and considering potential variations by specific cancer types in radiotherapy populations, this distribution is considered generally applicable.

(2) The patient age distribution was: 13% aged 21-40, 44.1% aged 41-60, 36.8% aged 61-80, and 6.1% aged 81-100. Given that radiotherapy patients are predominantly middle-aged and elderly (with 60%-70% typically over 60 years old according to ASTRO data), this distribution is assessed as highly applicable and meeting clinical needs.

(3) Regarding race, the sample comprised 78% White, 12% Black or African American, and 10% Others. This composition fully covers the key racial groups in U.S. clinical radiotherapy practice without omitting significant populations, thus deemed applicable.

(4) Concerning medical imaging equipment brands, MR images used for sCT generation were obtained from GE (21.6%), Philips (56.9%), and Siemens (21.6%) scanners. This demonstrates excellent applicability as these three brands collectively represent the entirety of the mainstream MRI scanner market in U.S. radiotherapy clinics, ensuring comprehensive coverage of image characteristic variations across different manufacturers. CBCT images used for sCT generation were sourced from Varian (58.8%) and Elekta (41.2%) equipment, also showing excellent applicability since these two manufacturers dominate the U.S. radiotherapy CBCT equipment landscape, fully reflecting the actual clinical scenario for setup verification.

| Organ & Structure | NO. | Size | DSC | | | | $HD_{95}$ (mm) | | | Average Rating (1-5) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Pass Criteria | DSC Mean | DSC STD | Lower Bound 95% CI | $HD_{95}$ Mean | $HD_{95}$ STD | Lower Bound 95% CI | |
| TemporalLobe_L | 37 | Medium | 0.65 | 0.898 | 0.036 | 0.886 | 4.58 | 0.824 | 4.319 | 4.5 |
| TemporalLobe_R | 37 | Medium | 0.65 | 0.892 | 0.043 | 0.878 | 4.67 | 0.905 | 4.382 | 4.6 |
| Brain | 47 | Large | 0.8 | 0.987 | 0.006 | 0.986 | 2.04 | 0.572 | 1.877 | 4.7 |
| BrainStem | 46 | Medium | 0.65 | 0.873 | 0.105 | 0.843 | 5.26 | 0.915 | 4.999 | 4.5 |
| SpinalCord | 103 | Medium | 0.65 | 0.873 | 0.032 | 0.867 | 3.20 | 0.865 | 3.030 | 4.8 |
| OpticChiasm | 36 | Small | 0.5 | 0.811 | 0.021 | 0.804 | 5.05 | 0.840 | 4.771 | 4.1 |
| OpticNerve_L | 36 | Small | 0.5 | 0.834 | 0.036 | 0.822 | 2.51 | 0.853 | 2.235 | 4.1 |
| OpticNerve_R | 36 | Small | 0.5 | 0.813 | 0.059 | 0.794 | 2.68 | 0.781 | 2.422 | 4.2 |
| InnerEar_L | 40 | Small | 0.5 | 0.852 | 0.028 | 0.843 | 2.40 | 0.771 | 2.164 | 4.2 |
| InnerEar_R | 39 | Small | 0.5 | 0.830 | 0.078 | 0.806 | 2.33 | 0.721 | 2.102 | 4.4 |
| MiddleEar_L | 40 | Small | 0.5 | 0.838 | 0.045 | 0.824 | 3.85 | 0.858 | 3.580 | 4.5 |
| MiddleEar_R | 41 | Small | 0.5 | 0.810 | 0.059 | 0.792 | 3.97 | 0.875 | 3.700 | 4.4 |
| Eye_L | 37 | Small | 0.5 | 0.929 | 0.070 | 0.906 | 1.83 | 0.530 | 1.659 | 4.8 |
| Eye_R | 37 | Small | 0.5 | 0.924 | 0.085 | 0.897 | 1.76 | 0.546 | 1.584 | 4.9 |
| Lens_L | 35 | Small | 0.5 | 0.852 | 0.048 | 0.836 | 3.62 | 0.760 | 3.368 | 4.5 |
| Lens_R | 35 | Small | 0.5 | 0.858 | 0.050 | 0.841 | 3.66 | 0.840 | 3.379 | 4.2 |
| Pituitary | 34 | Small | 0.5 | 0.826 | 0.073 | 0.801 | 2.55 | 0.829 | 2.267 | 4.4 |
| Mandible | 65 | Small | 0.5 | 0.922 | 0.035 | 0.913 | 2.01 | 0.677 | 1.844 | 4.3 |
| TMJ_L | 44 | Small | 0.5 | 0.842 | 0.043 | 0.830 | 3.06 | 0.820 | 2.819 | 4.4 |
| TMJ_R | 44 | Small | 0.5 | 0.830 | 0.045 | 0.817 | 2.96 | 0.814 | 2.722 | 4.5 |
| OralCavity | 66 | Medium | 0.65 | 0.926 | 0.044 | 0.916 | 3.90 | 0.916 | 3.677 | 4.7 |
| Larynx | 60 | Medium | 0.65 | 0.815 | 0.078 | 0.795 | 2.42 | 0.899 | 2.196 | 4.4 |
| Trachea | 57 | Medium | 0.65 | 0.895 | 0.096 | 0.870 | 2.69 | 0.932 | 2.452 | 4.5 |
| Esophagus | 72 | Medium | 0.65 | 0.812 | 0.053 | 0.800 | 2.89 | 0.919 | 2.680 | 4.7 |
| Parotid_L | 61 | Medium | 0.65 | 0.873 | 0.090 | 0.851 | 2.60 | 0.839 | 2.386 | 4.6 |
| Parotid_R | 62 | Medium | 0.65 | 0.882 | 0.058 | 0.868 | 2.53 | 0.819 | 2.328 | 4.6 |
| Submandibular_L | 57 | Medium | 0.65 | 0.848 | 0.058 | 0.833 | 5.13 | 0.794 | 4.920 | 4.5 |
| Submandibular_R | 56 | Medium | 0.65 | 0.811 | 0.107 | 0.783 | 2.56 | 0.813 | 2.348 | 4.3 |
| Thyroid | 57 | Medium | 0.65 | 0.822 | 0.073 | 0.803 | 2.11 | 0.774 | 1.911 | 4.8 |
| BrachialPlexus_L | 60 | Medium | 0.65 | 0.842 | 0.052 | 0.828 | 5.56 | 0.858 | 5.347 | 4.4 |
| BrachialPlexus_R | 60 | Medium | 0.65 | 0.821 | 0.082 | 0.800 | 5.29 | 0.890 | 5.062 | 4.3 |
| Lung_L | 54 | Large | 0.8 | 0.973 | 0.018 | 0.968 | 1.76 | 0.480 | 1.635 | 4.5 |
| Lung_R | 53 | Large | 0.8 | 0.980 | 0.015 | 0.976 | 1.66 | 0.523 | 1.516 | 4.7 |
| Heart | 53 | Large | 0.8 | 0.964 | 0.020 | 0.959 | 2.75 | 0.944 | 2.496 | 4.5 |
| Liver | 56 | Large | 0.8 | 0.949 | 0.032 | 0.941 | 2.63 | 0.727 | 2.439 | 4.0 |
| Kidney_L | 56 | Large | 0.8 | 0.912 | 0.080 | 0.892 | 2.97 | 0.837 | 2.748 | 4.7 |
| Kidney_R | 58 | Large | 0.8 | 0.917 | 0.084 | 0.895 | 3.02 | 0.871 | 2.797 | 4.5 |
| Stomach | 53 | Large | 0.8 | 0.827 | 0.166 | 0.782 | 5.00 | 0.927 | 4.754 | 4.1 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Pancreas | 49 | Medium | 0.65 | 0.843 | 0.055 | 0.827 | 6.53 | 0.938 | 6.271 | 4.0 |
| Duodenum | 59 | Medium | 0.65 | 0.826 | 0.045 | 0.815 | 6.66 | 0.849 | 6.447 | 4.1 |
| Rectum | 21 | Medium | 0.65 | 0.818 | 0.052 | 0.796 | 2.46 | 0.964 | 2.047 | 3.9 |
| BowelBag | 53 | Large | 0.8 | 0.839 | 0.116 | 0.808 | 7.60 | 0.822 | 7.380 | 4.0 |
| Bladder | 21 | Large | 0.8 | 0.955 | 0.029 | 0.943 | 2.33 | 0.574 | 2.082 | 4.5 |
| Marrow | 28 | Large | 0.8 | 0.901 | 0.033 | 0.889 | 2.12 | 0.745 | 1.842 | 4.6 |
| FemurHead_L | 21 | Medium | 0.65 | 0.953 | 0.007 | 0.950 | 2.65 | 0.917 | 2.261 | 4.5 |
| FemurHead_R | 21 | Medium | 0.65 | 0.951 | 0.024 | 0.941 | 2.79 | 0.757 | 2.466 | 4.6 |

Table 1: Test Results for synthetic CT generated from MR images

| **Organ & Structure** | **NO.** | **Size** | **DSC** | | | | **$HD_{95}$ (mm)** | | | **Average Rating (1-5)** |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | **Pass Criteria** | **DSC Mean** | **DSC STD** | **Lower Bound 95% CI** | **$HD_{95}$ Mean** | **$HD_{95}$ STD** | **Lower Bound 95% CI** | |
| TemporalLobe_L | 41 | Medium | 0.65 | 0.879 | 0.082 | 0.854 | 3.69 | 0.797 | 3.451 | 4.8 |
| TemporalLobe_R | 41 | Medium | 0.65 | 0.885 | 0.085 | 0.859 | 3.50 | 0.822 | 3.258 | 4.6 |
| Brain | 44 | Large | 0.8 | 0.988 | 0.007 | 0.986 | 2.03 | 0.769 | 1.804 | 4.7 |
| BrainStem | 41 | Medium | 0.65 | 0.909 | 0.020 | 0.903 | 4.92 | 0.790 | 4.678 | 4.5 |
| SpinalCord | 118 | Medium | 0.65 | 0.879 | 0.055 | 0.869 | 2.24 | 0.828 | 2.088 | 4.8 |
| OpticChiasm | 41 | Small | 0.5 | 0.807 | 0.040 | 0.795 | 5.51 | 0.826 | 5.252 | 4.4 |
| OpticNerve_L | 40 | Small | 0.5 | 0.827 | 0.038 | 0.815 | 2.65 | 0.887 | 2.373 | 4.2 |
| OpticNerve_R | 40 | Small | 0.5 | 0.827 | 0.036 | 0.816 | 2.46 | 0.798 | 2.210 | 4.1 |
| InnerEar_L | 41 | Small | 0.5 | 0.809 | 0.032 | 0.800 | 2.40 | 0.831 | 2.144 | 4.5 |
| InnerEar_R | 41 | Small | 0.5 | 0.804 | 0.032 | 0.794 | 2.41 | 0.783 | 2.171 | 4.2 |
| MiddleEar_L | 41 | Small | 0.5 | 0.812 | 0.038 | 0.800 | 3.57 | 0.867 | 3.301 | 4.5 |
| MiddleEar_R | 41 | Small | 0.5 | 0.805 | 0.026 | 0.797 | 4.18 | 0.963 | 3.888 | 4.5 |
| Eye_L | 41 | Small | 0.5 | 0.948 | 0.013 | 0.944 | 1.71 | 0.524 | 1.553 | 4.8 |
| Eye_R | 41 | Small | 0.5 | 0.945 | 0.012 | 0.941 | 1.84 | 0.534 | 1.678 | 4.9 |
| Lens_L | 41 | Small | 0.5 | 0.836 | 0.050 | 0.820 | 3.76 | 0.741 | 3.532 | 4.5 |
| Lens_R | 41 | Small | 0.5 | 0.844 | 0.072 | 0.821 | 3.65 | 0.898 | 3.370 | 4.7 |
| Pituitary | 39 | Small | 0.5 | 0.815 | 0.039 | 0.802 | 2.72 | 0.718 | 2.496 | 4.4 |
| Mandible | 42 | Small | 0.5 | 0.901 | 0.103 | 0.870 | 2.42 | 0.650 | 2.227 | 4.3 |
| TMJ_L | 40 | Small | 0.5 | 0.802 | 0.092 | 0.774 | 3.06 | 0.930 | 2.775 | 4.3 |
| TMJ_R | 41 | Small | 0.5 | 0.819 | 0.061 | 0.800 | 3.08 | 0.956 | 2.791 | 4.5 |
| OralCavity | 37 | Medium | 0.65 | 0.910 | 0.080 | 0.885 | 4.01 | 0.669 | 3.794 | 4.8 |
| Larynx | 33 | Medium | 0.65 | 0.803 | 0.032 | 0.793 | 3.20 | 1.089 | 2.827 | 4.8 |
| Trachea | 48 | Medium | 0.65 | 0.891 | 0.063 | 0.873 | 2.81 | 0.954 | 2.545 | 4.5 |
| Esophagus | 56 | Medium | 0.65 | 0.811 | 0.039 | 0.800 | 3.04 | 0.872 | 2.811 | 4.5 |
| Parotid_L | 41 | Medium | 0.65 | 0.900 | 0.030 | 0.891 | 2.66 | 0.799 | 2.415 | 4.6 |
| Parotid_R | 40 | Medium | 0.65 | 0.902 | 0.025 | 0.894 | 2.77 | 0.796 | 2.525 | 4.6 |
| Submandibular_L | 29 | Medium | 0.65 | 0.808 | 0.173 | 0.745 | 5.27 | 0.667 | 5.026 | 4.8 |
| Submandibular_R | 29 | Medium | 0.65 | 0.840 | 0.118 | 0.797 | 2.51 | 0.887 | 2.192 | 4.7 |
| Thyroid | 33 | Medium | 0.65 | 0.837 | 0.042 | 0.823 | 2.44 | 0.769 | 2.182 | 4.8 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| BrachialPlexus_L | 47 | Medium | 0.65 | 0.823 | 0.063 | 0.805 | 4.16 | 0.838 | 3.922 | 4.4 |
| BrachialPlexus_R | 47 | Medium | 0.65 | 0.833 | 0.036 | 0.823 | 3.80 | 0.955 | 3.529 | 4.2 |
| Lung_L | 57 | Large | 0.8 | 0.961 | 0.054 | 0.947 | 1.71 | 0.493 | 1.587 | 4.5 |
| Lung_R | 57 | Large | 0.8 | 0.978 | 0.027 | 0.971 | 1.75 | 0.429 | 1.635 | 4.3 |
| Heart | 58 | Large | 0.8 | 0.925 | 0.112 | 0.896 | 2.03 | 0.821 | 1.823 | 4.5 |
| Liver | 38 | Large | 0.8 | 0.927 | 0.043 | 0.914 | 2.82 | 0.702 | 2.595 | 4.6 |
| Kidney_L | 22 | Large | 0.8 | 0.932 | 0.024 | 0.922 | 3.02 | 0.888 | 2.645 | 4.7 |
| Kidney_R | 24 | Large | 0.8 | 0.929 | 0.057 | 0.906 | 2.97 | 0.898 | 2.611 | 4.5 |
| Stomach | 25 | Large | 0.8 | 0.871 | 0.035 | 0.858 | 5.01 | 0.844 | 4.681 | 4.2 |
| Pancreas | 21 | Medium | 0.65 | 0.838 | 0.036 | 0.822 | 5.84 | 0.674 | 5.548 | 4.4 |
| Duodenum | 23 | Medium | 0.65 | 0.831 | 0.031 | 0.818 | 5.68 | 1.048 | 5.252 | 4.1 |
| Rectum | 20 | Medium | 0.65 | 0.811 | 0.031 | 0.797 | 4.54 | 0.657 | 4.253 | 4.3 |
| BowelBag | 33 | Large | 0.8 | 0.863 | 0.038 | 0.850 | 5.39 | 1.051 | 5.028 | 4.0 |
| Bladder | 22 | Large | 0.8 | 0.949 | 0.055 | 0.926 | 3.59 | 0.650 | 3.322 | 4.7 |
| Marrow | 22 | Large | 0.8 | 0.882 | 0.109 | 0.837 | 2.54 | 0.948 | 2.148 | 4.7 |
| FemurHead_L | 20 | Medium | 0.65 | 0.935 | 0.097 | 0.893 | 1.88 | 0.546 | 1.639 | 4.8 |
| FemurHead_R | 20 | Medium | 0.65 | 0.945 | 0.042 | 0.927 | 2.04 | 0.539 | 1.807 | 4.9 |

Table 2: Test Results for sCT generated from CBCT

*Performance Test Report on 4DCT Registration Function*

The performance test report on 4DCT registration was performed to to evaluate the image conversion functionby DICE Assessment Method. We use the RTStruct contoured by the professional physician as the gold standard, the first frame of each 4DCT set was registered with frames 2 to 10 from the same patient. The contour of each Region of Interest (ROI) was then compared, and the Dice Similarity Coefficient (DSC) was calculated.And then calculate DSC Mean, DSC STD and Lower Bound 95% Confidence Interval for each ROI, analyze the Dice coefficient results.Additionally, the qualitative clinical appropriateness of AccuContour structures generated on these scans was graded by clinical experts. The generated structures were graded on a scale from 1 to 5 where 5 refers to contour requiring no additional edits, and 1 refers to a score in which full manual re-contour of the structure would be required. An average score≥3 was used to determine whether a structure model would ultimately be beneficial clinically. According to the results, the accuracy of 4DCT image registration images meets the requirements and all structure models demonstrating that only minor edits would be required in order to make the structure models acceptable for clinical use. The test results are presented in Table 3 and Table 4.

A total of 30 4DCT image sets were used in the test. The test data set information is as follows:

(1) The sample comprised images from Siemens (90.0%) and Philips (10.0%) scanners, representing major global vendors.
(2) Demographically, subjects included 17 males (56.7%) and 13 females (43.3%), aged 33-82 years, with the majority in the 51-65 (40.0%) and 66-80 (43.3%) year brackets.
(3) All images (100%) shared a uniform 3mm slice thickness. Most images (90.0%) were

sourced from Drexel Town Square Health Center/Community Memorial Hospital, with the remainder from Froedtert Hospital.

This distribution supports the sample's representativeness and technical consistency for the intended study.

| Organ & Structure | NO. | Size | Pass Criteria | DSC Mean | DSC STD | Lower Bound 95% CI | Average Rating (1-5) |
|---|---|---|---|---|---|---|---|
| Trachea | 25 | Medium | 0.650 | 0.907 | 0.030 | 0.888 | 4.5 |
| Esophagus | 30 | Medium | 0.650 | 0.860 | 0.037 | 0.836 | 4.5 |
| Lung_L | 29 | Large | 0.800 | 0.947 | 0.022 | 0.932 | 4.7 |
| Lung_R | 30 | Large | 0.800 | 0.945 | 0.025 | 0.929 | 4.8 |
| Lung_All | 30 | Large | 0.800 | 0.946 | 0.023 | 0.930 | 4.8 |
| Heart | 30 | Large | 0.800 | 0.931 | 0.022 | 0.917 | 4.6 |
| SpinalCord | 30 | Medium | 0.650 | 0.949 | 0.008 | 0.943 | 4.6 |
| Liver | 30 | Large | 0.800 | 0.912 | 0.037 | 0.888 | 4.6 |
| Stomach | 30 | Large | 0.800 | 0.841 | 0.076 | 0.791 | 4.5 |
| A_Aorta | 30 | Large | 0.800 | 0.928 | 0.016 | 0.917 | 4.4 |
| Spleen | 30 | Large | 0.800 | 0.834 | 0.075 | 0.786 | 4.5 |
| Body | 30 | Large | 0.800 | 0.997 | 0.002 | 0.995 | 4.9 |

Table 3: Test Results after Rigid Registration for Each ROI

| Organ & Structure | NO. | Size | Pass Criteria | DSC Mean | DSC STD | Lower Bound 95% CI | Average Rating (1-5) |
|---|---|---|---|---|---|---|---|
| Trachea | 25 | Medium | 0.650 | 0.946 | 0.008 | 0.940 | 4.7 |
| Esophagus | 30 | Medium | 0.650 | 0.901 | 0.054 | 0.866 | 4.6 |
| Lung_L | 29 | Large | 0.800 | 0.975 | 0.012 | 0.966 | 4.7 |
| Lung_R | 30 | Large | 0.800 | 0.998 | 0.076 | 0.949 | 4.5 |
| Lung_All | 30 | Large | 0.800 | 0.993 | 0.060 | 0.954 | 4.8 |
| Heart | 30 | Large | 0.800 | 0.971 | 0.060 | 0.931 | 4.6 |
| SpinalCord | 30 | Medium | 0.650 | 0.964 | 0.067 | 0.920 | 4.6 |
| Liver | 30 | Large | 0.800 | 0.978 | 0.064 | 0.936 | 4.5 |
| Stomach | 30 | Large | 0.800 | 0.915 | 0.039 | 0.889 | 4.5 |
| A_Aorta | 30 | Large | 0.800 | 0.951 | 0.006 | 0.947 | 4.6 |
| Spleen | 30 | Large | 0.800 | 0.932 | 0.031 | 0.913 | 4.8 |
| Body | 30 | Large | 0.800 | 0.998 | 0.001 | 0.997 | 4.9 |

Table 4: Test Results after Deformable Registration for Each ROI

Overall, the AccuContour was found to be safe and effective for all intended users, purpose and use environments.

**Mechanical and Acoustic Testing**

Not Applicable (Standalone Software).

**Animal Study**

Not Applicable (Standalone Software).

**Clinical Studies**

Clinical trials were not performed as part of the development of this product. Clinical testing on patients is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk.

## VIII. CONCLUSIONS

The subject device, AccuContour 4.0, is believed to be substantially equivalent to the predicate device in terms of its indications for use, technical characteristics, and overall performance. The information provided in this submission indicates its substantial equivalence to the predicate device.
Therefore, Manteia Technologies Co., Ltd. considered the subject AccuContour 4.0 is substantially equivalent to the predicate device AccuContour (K221706).