December 5, 2025

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

Re: K250780
Trade/Device Name: ARTAssistant
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: October 31, 2025
Received: October 31, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250780

Please provide the device trade name(s).

ARTAssistant

Please provide your Indications for Use below.

The primary function of ARTAssistant is to facilitate image processing with image registration and synthetic CT (sCT) generation in adaptive radiation therapy. This enables users to meticulously design ART plans based on the processed images.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

The following information is provided as required by 21 CFR 807.92.
The assign 510(k) Number: K250780

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: 12/04/2025

II. DEVICE

Device/Trade Name: ARTAssistant
Common or Usual Name: Adaptive radiotherapy assistant system
Classification Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QKB
Regulation Number: 21CFR 892.2050
Review Panel: Radiology

III. PREDICATE DEVICE

Predicate Device: AccuContour, K221706

Reference Device 1: MRI Planner, K211841
Reference Device 2: RayStation, K220141

IV. DEVICE DESCRIPTION

ARTAssistant, is a standalone software which is positioned as an adaptive radiotherapy auxiliary system, aiming to provide a complete solution to assist the implementation of adaptive radiotherapy, helping hospitals to implement adaptive radiotherapy on ordinary image-guided accelerators based on the current situation. This system is mainly used to assist in the image processing of online adaptive radiotherapy, thereby helping users complete the design of the daily adaptive radiotherapy plan based on the processed images.

The product has three main functions on image processing:
(1) Automatic registration: rigid and deformable registration, and

(2) Image conversion: generation of synthetic CT from CBCT or MR, and
(3) Image contouring: it can manual contour organs-at-risk, in head and neck, thorax, abdomen and pelvis (for both male and female) areas assisted contouring tools.

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.

V. INDICATIONS FOR USE

The primary function of ARTAssistant is to facilitate image processing with image registration and synthetic CT (sCT) generation in adaptive radiation therapy. This enables users to meticulously design ART plans based on the processed images.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

ITEM	Subject Device	Predicate Device K221706	Reference Device K211841	Reference Device K220141
Regulatory Information				
Regulation No.	21CFR 892.2050	21CFR 892.2050	21CFR 892.5050	21CFR 892.5050
Product Code	QKB	QKB	MUJ	MUJ
Class	II	II	II	II
Indications of Use	The primary function of ARTAssistant is to facilitate image processing with image registration and synthetic CT (sCT) generation in adaptive radiation therapy. This enables users to meticulously design ART plans based on the processed images.	It is used by radiation 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.	MRI Planner is a software-only medical device intended for use by trained radiation oncologists, dosimetrists and physicists to process images from MRI systems to 1) provide the operator with information of tissue properties for radiation attenuation estimation purposes in photon external beam radiotherapy treatment planning, and to 2) derive contours for input to radiation treatment planning by assisting in localization and definition of healthy anatomical structures. MRI Planner is not intended to automatically contour tumors or	RayStation is a software system for radiation therapy and medical oncology. Based on user input, RayStation proposes treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, RayStation may also be used to administer treatments. The system functionality can be configured based on user needs.

ITEM	Subject Device	Predicate Device K221706	Reference Device K211841	Reference Device K220141
			tumor clinical target volumes. MRI Planner is indicated for radiotherapy planning of adult patients for primary and metastatic cancers in the brain and head-neck regions, as well as soft tissue cancers in the pelvic region. MRI Planner generates synthetic CT images for radiation attenuation estimation purposes for the pelvis, brain and head-neck regions only. MRI Planner generates automatically derived contours of the bladder, colon and femoral heads, for prostate cancer patients only.	
Operating System	Windows	Windows	Windows	Windows
Technological Characteristics				
Auto Rigid Registration Algorithm	Intensity based	Intensity based	N/A	N/A
Auto Deformable Registration Algorithm	Intensity based	Intensity based	N/A	N/A
Image Conversion Algorithm	Deep learning	N/A	Machine Learning	Machine Learning

ITEM	Subject Device	Predicate Device K221706	Reference Device K211841	Reference Device K220141
Registration Feature				
Image Registration	Auto rigid registration and auto deformable registration	Auto rigid registration and auto deformable registration	N/A	N/A
Compatible Modality	Auto rigid registration: CT, MRI, PET Auto deformable registration: CT, MRI, CBCT	Auto rigid registration: CT, MRI, PET Auto deformable registration: CT, MRI, CBCT	N/A	N/A
Compatible Scanner Models	No Limitation on scanner model, DICOM 3.0 compliance required	No Limitation on scanner model, DICOM 3.0 compliance required	N/A	N/A
Image Conversion Feature				
Image Conversion	Generates synthetic CT from both MR and CBCT	N/A	Generates synthetic CT from MR	Generates synthetic CT from CBCT
Image Enhance Feature				
CBCT Image Enhance	YES	N/A	YES	N/A
Image Contouring Feature				
Manual Contouring	YES	YES	N/A	N/A
Compatible Scanner Models	No Limitation on scanner model, DICOM 3.0 compliance required	No Limitation on scanner model, DICOM 3.0 compliance required	N/A	N/A
Contour QA	YES	YES	N/A	N/A

VII. PERFORMANCE DATA

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

Biocompatibility Testing

ARTAssistant is a software only device and will not come in contact with the patient, thus biocompatibility testing is not applicable.

Electrical Safety and Electromagnetic Compatibility (EMC)

ARTAssistant is a software only device, and no Electrical safety and electromagnetic compatibility testing was conducted for the Subject Device.

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. ARTAssistant passed all software verification and validation tests.

Performance Test Report on Rigid Registration Function

The automatic rigid registration algorithm performance test was performed against the reference device (K221706) to evaluate the rigid registration accuracy. All fixed images and moving images were generated in healthcare institutions in U.S. The scanner models covered five major vendors. And the image registration feature is only tested on multi-modality image sets from different patients. The Normalized Mutual Information (NMI) and Hausdorff Distance (HD) were used for evaluation. NMI and HD values were calculated on two sets of images for both the proposed device and predicate device (K221706), respectively. The NMI and HD values of the subject device was compared with that of the predicate device. According to the results, it could be concluded that the NMI and HD values of the proposed device was non-inferiority compares with that of the predicate device.

Performance Test Report on Deformable Registration Function

The automatic deformable registration algorithm performance test was performed against the reference device (K221706) to evaluate the deformable registration accuracy. All fixed images and moving images were generated in healthcare institutions in U.S. The scanner models covered five major vendors. And the image registration feature is only tested on multi-modality image sets from different patients. The Normalized Mutual Information (NMI) and Hausdorff Distance (HD) were used for evaluation. NMI and HD values were calculated on two sets of images for both the proposed device and predicate device (K221706),

respectively. The NMI and HD values of the subject device was compared with that of the predicate device. According to the results, it could be concluded that the NMI and HD values of the proposed device was non-inferiority compares with that of the predicate device.

Performance Test Report on Image Conversion Function

The performance test on image conversion function was carried out to evaluate the accuracy of image conversion function for the test article, ARTAssistant, by using TG119 methodTest images included in this study were all generated in U.S., and covered 6 cancer types including intracranial tumor, nasopharyngeal carcinoma, esophagus cancer, lung cancer, liver cancer and cervical cancer. After generating SCT from MR/CBCT images, the gamma value of RTDose is compared with the gamma value of sRTDose, and Gamma Pass Rate of all test results is within the acceptable range of AAPM TG-119, which demonstrates the accuracy of the image conversion function. Additionally, another performance test of the image conversion function was conducted to evaluate the anatomic and geometric accuracy of synthetic CT (sCT) generated from CBCT and MR. This involved comparing the segmentation results of each ROI on CBCT/MR against those on sCT and calculating the Dice similarity coefficient. The results indicate that the geometric accuracy of sCT images generated from both CBCT and MR meets the requirements.

For the deep learning model for image conversion there were 560 training and 247 testing image sets. The training image set source is from China, and the testing image source is from the United States. They are independent of each other.

The test data set information is as follows:

(1) Among the patients used for CT testing 57% were male and 43% female. Patient ages range 21-40:13%, 41-60 : 44.1%, 61-80: 36.8%, 81-100:6.1%%. Race：78% White, 12% Black or African American, 10% Other.
(2) Test datasets spanned across treatment subgroups most typically found in 4 radiation therapy treatment clinics. MR/CT test dataset covers Intracranial Tumor (13.8%), Nasopahryngeal Carcinoma (19%), Esophagus Cancer (19%), Lung Cancer (17.2%), Liver Cancer (12.9%), Cervical Cancer(18.1%); CBCT/CT test dataset covers Intracranial Tumor (16.8%), Nasopahryngeal Carcinoma (16.8%), Esophagus Cancer (16.8%), Lung Cancer (16.8%), Liver Cancer(16%),Cervical Cancer(16.8%).
(3) The CT images were obtained using scanners supplied by GE/Philips/Siemens, including 28.3% by GE, 41.7% by Philips and 30% by Siemens. The MR images were obtained using scanners supplied by GE/Philips/Siemens, including 21.6% by GE, 56.9% by Philips and 21.6% by Siemens.The CBCT images were obtained using scanners supplied by Varian/Elekta, including 58.8% by Varian, 41.2% by Elekta .And the images contained different slice thicknesses, distributed as follows: 19% 1mm, 22.8% 2mm, 17.4% 2.5mm, 17% 3mm, 23.8% 5mm slice thickness.

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

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