Manteia Technologies Co., Ltd.
% Dandan Chen
RA
1903, B Tower, Zijin Plaza
No. 1811 Huandao East Road
Xiamen, 361001
CHINA

March 9, 2023

Re: K221706
Trade/Device Name: AccuContour
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QKB
Dated: May 31, 2022
Received: June 13, 2022

Dear Dandan Chen:

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,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.03.09 19:17:29 -05'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
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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)*
K221706

Device Name
AccuContour

Indications for Use *(Describe)*
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.

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

Ⅰ. SUBMITTER

Manteia Technologies Co., Ltd.
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China Establishment Registration Number: 3016686005

Contact Person: Dandan Chen
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Date Prepared: March 9, 2023

Ⅱ. DEVICE

Name of Device: AccuContour
Common or Usual Name: Medical Imaging Software
Classification Name: System, Imaging processing, Radiological
Regulatory Class: Ⅱ
Product Code: QKB
Regulation Number: 21CFR 892.2050
Review Panel: Radiology

Ⅲ. PREDICATE DEVICE

Device	510(k) Number	Product Name
Predicate Device	K191928	AccuContour™
Reference Device	K182624	MIM-MRT Dosimetry
Reference Device	K173636	Velocity
Reference Device	K181572	Workflow Box

Ⅳ. DEVICE DESCRIPTION

The proposed device, AccuContour, is a standalone software which 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.

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 of processed images;
- Extension tool;
- Plan evaluation and plan comparison;
- Dose analysis.

Ⅴ. INDICATIONS FOR USE

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.

Ⅵ. SUBSTANTIALLY EQUIVALENT (SE) COMPARISION

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K191928	Reference Device K182624	Reference Device K173636	Reference Device K181572
Regulatory Information					
Regulation No.	21CFR 892.2050	21CFR 892.2050	21CFR 892.2050	21CFR 892.2050	21CFR 892.2050
Product Code	QKB	QKB	LLZ	LLZ	LLZ
Indication for Use	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.	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.	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.	Velocity is a software package that provides the physicians a means for comparison of medical data including imaging data that is DICOM compliant. It allows the display, annotation, volume operation, volume rendering, registration, and fusion of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. Velocity is not intended for mammography.	Workflow Box is a software system designed to allow users to route DICOM-compliant data to and from automated processing components. Supported modalities include CT, MR, RTSTRUCT. Workflow Box includes processing components for automatically contouring imaging data using deformable image registration to support atlas based contouring, re-contouring of the same patient and machine learning based contouring. Workflow Box is a data routing and image processing tool which automatically applies contours to

			• 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 transferring contours to		data which is sent to one or more of the included image processing workflows. Contours generated by Workflow Box may be used as an input to clinical workflows including, but not limited to, radiation therapy treatment planning. Workflow Box must be used in conjunction with appropriate software to review and edit results generated automatically by Workflow Box components, for example image visualization software must be used to facilitate the review and edit of contours generated by Workflow Box component applications. Workflow Box is intended to be used by trained medical professionals. Workflow Box is not intended to automatically detect lesions.

			radiation 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 a 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.		
Label/labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Conform with 21CFR Part 801
Operating System	Windows	Windows	Windows and MAC system	Windows and MAC system	Windows
Segmentation Features					
Algorithm	Deep Learning	Deep Learning	Atlas-based	Atlas-based	Atlas Based contouring,

					registration based re-contouring, machine learning based contouring
Compatible Modality	Non-Contrast CT	Non-Contrast CT	Non-Contrast CT	Non-Contrast CT	CT、MR
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.	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 TPS model, DICOM 3.0 compliance required.	No Limitation on TPS model, DICOM 3.0 compliance required.	No Limitation on TPS model, DICOM 3.0 compliance required.	No Limitation on TPS model, DICOM 3.0 compliance required.	No Limitation on TPS model, DICOM 3.0 compliance required.
Unattended workstation	Yes	No	Not stated	No	Yes
Registration Features					
Algorithm	Intensity Based.	Intensity Based.	Intensity Based.	Intensity Based.	Intensity Based.
Image registration	Auto rigid registration and auto deformable registration.	Auto rigid registration	Auto rigid registration and deformable registration.	Auto rigid registration and deformable registration.	Auto rigid registration and deformable registration.
Compatible Modality	Auto rigid registration: CT, MRI, PET Auto deformable registration: CT, MRI, CBCT	CT, MRI, PET	CT, MRI, CR, DX, MG, US, SPECT, PET and XA	PET/SPECT/CT/MRI	CT, MRI

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.	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.	No Limitation on scanner model, DICOM 3.0 compliance required.	No Limitation on scanner model, DICOM 3.0 compliance required.
Plan Evaluation Feature					
Display of DICOM RT Plans	Yes	No	Not stated	Yes	No
Isodose Line Display	Yes	No	Not stated	Yes	No
DVH statistics display	Yes	No	Not stated	Yes	No
RT Plans comparison	Yes	No	Not stated	Yes	No
Dose Analysis Feature					
Display of DICOM RT Doses	Yes	No	Not stated	Yes	No
Dose accumulation	Yes	No	Not stated	Yes	No

Ⅶ. PERFORMANCE DATA

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

1. Non-Clinical Test Conclusion

Deformable registration performance test

The registration performance test was performed on proposed device and reference device (K182624) to evaluate the deformable registration accuracy. All fixed images and moving images are generated in healthcare institutions in U.S. The scanner models covered products from five major vendors. The image registration feature is tested on multi-modality image sets from different patients. The Normalized Mutual Information (NMI) was used for evaluation. NMI values were calculated on two sets of images for both the proposed device and reference device (K182624), respectively. The NMI value of proposed device was compared with that of the reference device. According to the results, it could be concluded that the NMI of proposed device was non-inferior to that of the reference device.

2. Clinical Test Conclusion

No clinical study is included in this submission.

3. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern.

Software bench testing in the form of Unit, System and Integration tests were performed to evaluate the performance and functionality of the new features and software updates. Software verification and regression testing have been performed successfully to meet their previously determined acceptance criteria as stated in the test plans.

Ⅷ. SUBSTANIALLY EQUIVALENT (SE) CONCLUSION

The proposed device is substantially equivalent to the predicate device AccuContour™ (K191928).