Xiamen Manteia Technology LTD.
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co. Ltd.
P.O Box 120-119
Shanghai, 200120
CHINA

February 28, 2020

Re: K191928
Trade/Device Name: AccuContour™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QKB
Dated: January 10, 2020
Received: January 17, 2020

Dear Ms. Hong:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191928

Device Name
AccuContour

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K191928

1. Date of Preparation: 02/26/2020

2. Sponsor Identification

Xiamen Manteia Technology LTD.
1903, B Tower, Zijin Plaza, No.1811 Huandao East Road, Xiamen, China

Establishment Registration Number: Not registered yet.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: AccuContour™
Common Name: Medical Imaging Software

Regulatory Information

Classification Name: System, Imaging processing, Radiological
Classification: II;
Product Code: QKB
Regulation Number: 21CFR 892.2050
Review Panel: Radiology;

Indication for Use Statement:

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.

Device Description:

The proposed device, AccuContour™, 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.

5. Identification of Predicate Device

510(k) Number: K182624
Product Name: MIM-MRT Dosimetry

6. Non-Clinical Test Conclusion

Segmentation performance test

The segmentation performance test was performed on proposed device and predicate device to evaluate the automated segmentation accuracy. Two separate tests were performed. One test involved images generated in healthcare institutions in China using scanner models available in China covering three major vendors. The other involved images generated in healthcare institutions in US using scanner models available in US covering three major vendors. The three major vendors were GE, Siemens and Philips. For each body parts, all intended organs were included in images of the US and China. Ground truthing of each image was generated from the consensus of at least three licensed physicians. DICE similarity coefficients (DSC) was used for evaluation. DSC values were calculated on two sets of images for test group and control group, respectively. According to the results, it could be concluded that the DSC of proposed device was non-inferiority compared with that of the predicate device.

Registration performance test

The registration performance test was performed on proposed device and predicate device to evaluate the automated registration accuracy. Two separate tests were performed. One test involved images generated in healthcare institutions in China using scanner models available in China covering three major vendors. And the image registration feature is tested on multi-modality image sets from same patients. The other involved most images generated in healthcare institutions in U.S. All fixed image and most moving images came from U.S and a small amount of moving images adopted from online database were originally from non-US sources. All the scanner models covered three major vendors. And the image registration feature is only tested on multi-modality image sets from different patients. Both tests covered various modalities, including CT/CT, CT/MR and CT/PET. The Normalized Mutual Information (NMI) was used for evaluation. NMI values were calculated on two sets of images for both the proposed device and predicate device, respectively. The NMI value of proposed device was compared with that of the predicate device. According to the results, it could be concluded that the NMI of proposed device was non-inferiority compared with that of the predicate device.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K182624
Regulatory Information		
Regulation No.	21CFR 892.2050	21CFR 892.2050
Product Code	QKB	LLZ
Class	II	II
Indication for Use	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.	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

ITEM	Proposed Device	Predicate Device K182624
		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
Operating System	Windows	Windows and MAC system
Segmentation Features		
Algorithm	Deep Learning	Atlas-based
Compatible Modality	Non-Contrast CT	Non-Contrast CT
Compatible Scanner Models	No Limitation on scanner model, DICOM 3.0 compliance required.	No Limitation on scanner model, DICOM3.0 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.
Contraindications	None	None

ITEM	Proposed Device	Predicate Device K182624
Registration Features		
Algorithm	Intensity Based	Intensity Based
Compatible Modality	CT, MRI, PET	CT, MRI, CR, DX, MG, US, SPECT, PET and XA
Compatible Scanner Models	No Limitation on scanner model, DICOM 3.0 compliance required.	No Limitation on scanner model, DICOM3.0 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.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.