Manteia Technologies Co., Ltd.
Chao Fang
RA
1903-1904, B Tower, Zijin Plaza,
No.1811 Huandao East Road
Xiamen, Fujian 361001
CHINA

July 10, 2023

Re: K223724
Trade/Device Name: MOZI TPS
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: January 1, 2023
Received: January 3, 2023

Dear Mr. 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 (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: 2023.07.10 17:31:17 -04'00'

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)*
K223724

Device Name
MOZI TPS

Indications for Use *(Describe)*
The MOZI Treatment Planning System (MOZI TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. MOZI TPS is used to plan external beam irradiation with photon beams.

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.

510(k) Summary

The following information is provided as required by 21 CFR 807.92.
The assign 510(k) Number: K223724

1. SUBMITTER

Name and Address:	**Manteia Technologies Co., Ltd.** 1903-1904, B Tower, Zijin Plaza, No.1811 Huandao East Road, Xiamen, China
Establishment Registration Number:	3016686005
Contact Person:	Chao Fang RA&QA Manager Email: fangchao@manteiatech.com
Date of Preparation:	July 9, 2023

2. DEVICE

Device/Trade Name:	MOZI TPS
Common Name:	MOZI Treatment Planning System (MOZI TPS)
Product Classification:	Class II
Classification Name:	System, Planning, Radiation Therapy Treatment
Product Code:	MUJ
Regulation Number:	21CFR 892.5050
Regulation Description:	Medical charged-particle radiation therapy system

3. PREDICATE DEVICE

Predicate Device:	K172163 (Eclipse Treatment Planning System (Eclipse TPS))
Reference Device 1:	K191928 (AccuContour™)
Reference Device 2:	K182624 (MIM-MRT Dosimetry)

4. Device Description:

The proposed device, MOZI Treatment Planning System (MOZI TPS), is a standalone software which is used to plan radiotherapy treatments (RT) for patients with malignant or benign diseases.

Its core functions include image processing, structure delineation, plan design, optimization and evaluation. Other functions include user login, graphical interface, system and patient management. It can provide a platform for completing the related work of the whole RT plan.

The product uses generally accepted methods for below automatic function:

- automatic rigid and deformable registration of image processing
- dose calculation with Monte Carlo method of plan design and optimization

And it also uses deep learning method for automatic contouring of structure delineation.

5. INDICATIONS FOR USE

The **MOZI Treatment Planning System** (MOZI TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. MOZI TPS is used to plan external beam irradiation with photon beams.

6. SUBSTANTIALLY EQUIVALENT(SE) COMPARISON

The Subject Device, MOZI TPS, makes use of a Predicate Device, Eclipse TPS(K172163), as the Predicate Device for substantial equivalence comparison, and Reference Device 1, AccuContour™(K191928), and Reference Device 2, MIM-MRT Dosimetry(K182624), as Reference Device for performance comparison on automatic function of rigid registration, deformable registration and contouring. In addition, the subject device adopts the same algorithm as AccuContour™(K191928) on automatic function of rigid registration and contouring.

At a high level, both the predicate device and the subject device are based on the same characteristics:

- Both the subject device and the predicate provide software tools for planning the treatment of malignant or benign diseases with radiation.
- They are computer-based software devices used by trained medical professionals to design and simulate radiation therapy treatments.
- They are both capable of planning treatments for external beam irradiation with photon.

The significant differences compared with the predicate device are as follows:

1. The intended use range of subject device is less than predicate device, which has been clearly stated in the intended use of subject device.
2. For dose calculation, the subject device incorporates a Monte Carlo based algorithm while the predicate device an AAA/AXB based algorithm. Both have been verified to be substantially equivalent by a performance test.
3. Performance test report on automatic rigid registration and contouring has been performed in subject device and reference device 1, AccuContour™(K191928). The test result is acceptable.
4. Performance test on automatic deformable has been performed in subject device and reference device 2, MIM-MRT Dosimetry(K182624). The test result is acceptable.

The following comparison table “Device Comparison Table” provides a detailed comparison.

Device Comparison Table

ITEM	Subject Device	Predicate Device K172163	Reference Device K191928	Reference Device K182624
Regulatory Information				
Regulation No.	21CFR 892.2050	21CFR 892.2050	21CFR 892.2050	21CFR 892.2050
Product Code	MUJ	MUJ	QKB	LLZ
Class	II	II	II	II
Indication for Use	The MOZI Treatment Planning System (MOZI TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. MOZI TPS is used to plan external beam irradiation with photon beams.	The Eclipse Treatment Planning System (Eclipse TPS) is used to plan radiotherapy treatments for patients with malignant or benign diseases. Eclipse TPS is used to plan external beam irradiation with photon, electron and proton beams, as well as for internal Irradiation (brachytherapy) treatments. In addition, the Eclipse Proton Eye algorithm is specifically indicated for planning proton treatment of neoplasms of the eye.	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. • Registration, fusion display, and review of medical images for diagnosis, treatment evaluation,

				and treatment planning. • Evaluation of cardiac left ventricular function and perfusion. • Localization and definition of objects such as tumors and normal tissues in medical images.
Label/labeling	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	Windows and MAC
Technological Characteristics				
Dose calculation algorithms	Monte Carlo (photon)	AAA、AXB	N/A	N/A
Auto rigid registration algorithms	Intensity based	Intensity based	Intensity based	Intensity based
Auto deformable registration algorithms	Intensity based	Intensity based	Intensity based	Intensity based
Auto segmentation algorithms	Deep learning	Atlas based	Deep learning	Atlas based
Graphical User Interface Features				
Multiple-instance application	Yes	Yes	N/A	N/A
Multiple-workspace layout	Yes	Yes	N/A	N/A
Graphical display/editing of field parameters	Yes	Yes	N/A	N/A
Beam's-Eye-View display	Yes	Yes	N/A	N/A
3D patient image display	Yes	Yes	N/A	N/A
Dose-Volume Histogram display	Yes	Yes	N/A	N/A
Patient Management Features				
DICOM RT	Yes	Yes	N/A	N/A

	(the device supports RT Image/ RT Structure/ RT Plan/ RT Dose)	(the device supports RT Image/ RT Structure/ RT Plan/ RT Dose)		
Import/Delete/Export/Edit/Retrieve patient data	Yes	Yes	N/A	N/A
Image Processing Features				
CT/MR manual image registration	Yes	Yes	Yes	Yes
Auto rigid registration	Yes (Intensity Based)	Yes (Intensity Based)	Yes (Intensity Based)	Yes (Intensity Based)
Auto deformable registration	Yes (Intensity Based)	Yes (Intensity Based)	Yes (Intensity Based)	Yes (Intensity Based)
Structure Delineation Features				
Automatic CT segmentation tool	Yes (deep learning)	Yes (Atlas based)	Yes (deep learning)	Yes (Atlas based)
Manual CT segmentation tool	Yes	Yes	Yes	Yes
Plan Design & Plan Optimization Features				
Photon Calculation	Yes	Yes	N/A	N/A
- Energy Range	1 MeV – 20 MeV	1 MeV – 50 MeV	N/A	N/A
- 3-dimensional conformal radiation therapy Planning	Yes	Yes	N/A	N/A
- Intensity modulated radiotherapy Planning	Yes	Yes	N/A	N/A
- Volumetric modulated arc therapy Planning	Yes	Yes	N/A	N/A
- Directional heterogeneity correction	Yes	Yes	N/A	N/A
- Treatment Head modelling	Yes	Yes	N/A	N/A
- Dose Dynamic Arc planning	Yes	Yes	N/A	N/A

- IMRT optimization	Yes	Yes	N/A	N/A
- VMAT optimization	Yes	Yes	N/A	N/A
- Dose Calculation	Yes (Monte Carlo)	Yes (AAA、AXB)	N/A	N/A
- Plan normalization	Yes	Yes	N/A	N/A
Plan Evaluation Features				
Create QA plan	Yes	Yes	N/A	N/A
Plan evaluation tools	Yes	Yes	N/A	N/A
Isodose levels display	2D	2D, 3D	N/A	N/A
Reference point dose summary	Yes	Yes	N/A	N/A
Dose Volume Histogram plot	Yes	Yes	N/A	N/A
Plan summing tool	Yes	Yes	N/A	N/A
Plan comparison tools	Yes	Yes	N/A	N/A
Planar dose export	Yes	Yes	N/A	N/A
Planning report output	Yes	Yes	N/A	N/A
- Graphics window screen dump	Yes	Yes	N/A	N/A
- Image set information	Yes	Yes	N/A	N/A
- Contouring Structural information	Yes	Yes	N/A	N/A
- Patient administration data	Yes	Yes	N/A	N/A
- Patient orientation	Yes	Yes	N/A	N/A
- Plan parameters	Yes	Yes	N/A	N/A
- Geometrical displays of plan data	Yes	Yes	N/A	N/A
- Field information	Yes	Yes	N/A	N/A
- Dose distribution	Yes	Yes	N/A	N/A
- DVH plot	Yes	Yes	N/A	N/A

7. PERFORMANCE DATA

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

Sterilization & Shelf-life Testing

MOZI TPS is a software device and is not supplied sterile because the device doesn't come in contact with the patient. MOZI TPS is a software device and does not have a Shelf Life.

Biocompatibility

MOZI TPS is a software device and does not come in contact with the patient.

Electrical safety and electromagnetic compatibility (EMC)

MOZI TPS is a software device hence, no Electromagnetic Compatibility and Electrical Safety testing was conducted for the Subject Device.

Software Verification and Validation Testing (Non-Clinical 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 verification and validation testing was performed according to the FDA Quality System Regulation (21 CFR Part 820), ISO 13485 Quality Management System standard, IEC 62304 Software Life Cycle standard, and ISO 14971 Risk Management Standard.

Commissioning test of Intensity-modulated radiation treatment planning system

The commissioning test was performed to verify the IMRT/VMAT performance of the subject device according to AAPM TG-119 Report. The Monte Carlo dose computation algorithm in subject device has been successfully validated for accuracy in clinically relevant settings according to specification.

Radiotherapy Treatment Planning System Software performance test

The performance test was performed on subject device and predicate device (K172163) to evaluate the performance in formulating external irradiation photon therapy plan. The subject device and predicate device both support Dose Calculation feature, the subject device incorporates a Monte Carlo based algorithm while the predicate device an AAA/AXB based algorithm. However, Monte Carlo、AAA、AXB are all universally acknowledged algorithm on dose calculation. And the algorithm used in subject device has been verified for its performance comparing against that of the predicate device, the result demonstrated that they have equivalent performance.

Deformable registration performance test

The automatic deformable registration algorithm performance test was performed against the reference device (K182624) 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 (K182624), 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.

Standards conformance test

A verification test was performed on subject device to verify the compliance of IEC 62083-2009 Standard. It is verified that the subject device has met the requirements for the safety of radiotherapy treatment planning systems.

End-to-end test

We conducted end-to-end test for 18 patients' treatment planning including the Simulation CT images import to the TPS, details of the contouring and image registration, step by step processes of the treatment planning and the optimization for IMRT and VMAT treatments, dose calculations, exporting the treatment plans to the LINAC software for delivery, and validation of the TPS with phantom measurement. The treatment planning in the test contains the cases with lung, liver, brain, and Head & Neck cancers using the IMRT and VMAT techniques. The test results are all passed that the entire workflow for the treatment planning have been adequately validated prior to the treatment of patients.

Structure delineation performance test

Mean Dice Similarity Coefficient (DSC) was used to evaluate the performance of Segmentation Function. The segmentation function of subject device has been verified for its performance comparing against that of the reference device K191928, by the DSC assessment method. The result demonstrated that they have equivalent performance.

The DSC values of the subject device's auto segmentation on the testing image set with 38 sample size are as follows:

Body Part	OAR	Mean DSC values	Mean standard deviation
Head&Neck	Brain	0.98	0.01
	Brainstem	0.88	0.03
	BrachialPlexus_L	0.61	0.05
	BrachialPlexus_R	0.64	0.05
	Esophagus	0.84	0.02
	Eye-L	0.93	0.02

	Eye-R	0.93	0.02
	InnerEar-L	0.78	0.06
	InnerEar-R	0.82	0.04
	Larynx	0.87	0.02
	Lens-L	0.77	0.07
	Lens-R	0.72	0.08
	Mandible	0.90	0.02
	MiddleEar_L	0.73	0.04
	MiddleEar_R	0.74	0.04
	OpticNerve_L	0.61	0.07
	OpticNerve_R	0.62	0.08
	OralCavity	0.90	0.03
	OpticChiasm	0.64	0.10
	Parotid-L	0.83	0.03
	Parotid-R	0.83	0.04
	PharyngealConstrictors_U	0.87	0.03
	PharyngealConstrictors_M	0.88	0.02
	PharyngealConstrictors_L	0.87	0.03
	Pituitary	0.74	0.14
	SpinalCord	0.85	0.04
	Submandibular_L	0.86	0.04
	Submandibular_R	0.87	0.03
	TemporalLobe_L	0.89	0.03
	TemporalLobe_R	0.89	0.03
	Thyroid	0.86	0.03
	TMJ_L	0.79	0.06
	TMJ_R	0.74	0.06
	Trachea	0.90	0.02
Thorax	Esophagus	0.80	0.05
	Heart	0.98	0.01
	Lung_L	0.99	0.00
	Lung_R	0.99	0.00
	Spinal Cord	0.97	0.02
	Trachea	0.95	0.02
Abdomen	Duodenum	0.64	0.05
	Kidney_L	0.96	0.02
	Kidney_R	0.97	0.01
	Liver	0.95	0.02
	Pancreas	0.79	0.04
	SpinalCord	0.82	0.02
	Stomach	0.89	0.02
Pelvic-Man	Bladder	0.92	0.03
	BowelBag	0.89	0.04

	FemurHead_L	0.96	0.02
	FemurHead_R	0.95	0.02
	Marrow	0.90	0.02
	Prostate	0.85	0.04
	Rectum	0.88	0.03
	SeminalVesicle	0.72	0.07
Pelvic-Female	Bladder	0.88	0.02
	BowelBag	0.87	0.02
	FemurHead_L	0.96	0.02
	FemurHead_R	0.95	0.02
	Marrow	0.89	0.02
	Rectum	0.77	0.04

For CT structure models there were 560 training and 187 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 21-30 : 0.3%, 31-50 : 31%, 51-70 : 51.3%, 71-100 : 14.4%. Race 78% White, 12% Black or African American, 10% Other.

(2) CT datasets spanned across treatment subgroups most typically found in a radiation therapy treatment clinic with the most common diagnosis being cancers of the Head and Neck (20.3%), Esophageal and Lung (Thorax, 20.3%), Gastrointestinal (Abdomen, 20.3%), Prostate (Male Pelvis, 20.3%), Other (Female Pelvis, 18.7%).

(3) The images were obtained using scanners supplied by GE/Philips/Siemens, including 28.3% by GE, 33.7% by Philips and 38% by Siemens. And the images contained different slice thicknesses, distributed as follows: 5.3% 1mm, 28.3% 2mm, 2.7% 2.5mm, 23% 3mm, 40.6% 5mm slice thickness.

Ground truthing of test data set was generated manually using consensus RTOG guidelines as appropriate by six clinically experienced radiation therapy physicists.

Cybersecurity Study

The cybersecurity of the subject device has been comprehensively risk assessed and tested, and has traceability. Corresponding supporting documents are provided in this submission.

Mechanical and Acoustic Testing

Not Applicable (Standalone Software).

Animal Study

No animal studies were conducted using the Subject Device, MOZI TPS.

Human Clinical Performance Testing

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.

8. CONCLUSION

Based on this Discussion and Testing and Performance Data, the subject device is determined to be as safe and effective as its predicate device Eclipse TPS (K172163)， and performs as well in automatic rigid registration and structure delineation as the reference device 1, AccuContour™ (K191928), the subject device also performs as well in automatic deformable registration as the reference device 2, MIM-MRT Dosimetry (K182624).