MedMind Technology Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
CHINA

December 15, 2021

Re: K213155
Trade/Device Name: RT-Mind-AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QKB
Dated: September 18, 2021
Received: September 28, 2021

Dear Diana 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213155

Device Name
RT-Mind-AI

Indications for Use *(Describe)*

It is used by radiation oncology department to 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: K213155

1. Date of Preparation: 12/08/2021

2. Sponsor Identification

MedMind Technology Co., Ltd.
A502-503, Techart Plaza, No.30, Xueyuan Road, Haidian District, Beijing, 100083, China.

Establishment Registration Number: Not registered yet.

Contact Person: Shaobin Wang
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: RT-Mind-AI
Common Name: Medical Imaging Software

Regulatory Information

Classification Name: Medical Image Management and Processing System
Classification: II;
Product Code: QKB;
Regulation Number: 21CFR 892.2050
Review Panel: Radiology;

Indication for Use:
It is used by radiation oncology department to segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation

Device Description

The proposed device, RT-Mind-AI, is a standalone software which used by radiation oncology department to segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation.

The proposed device has four main function:

1) Deep learning contouring:
   - Automatic segment on desktop: it can automatically contour the organ-at-risk (ORA), including Head and Neck, thorax and abdominal and pelvic.
   - Automatic segment on the Web: it can realize automatic contouring the OAR on the web and sending to the specified network node in a local area network (LAN). Note: only the administrator account and operator accounts can carry out the automatic segment on the Web.
2) Manual segment: Adjust the segment result after automatic segment.

It also has the following general functions:

- Preset ROIs
- Preset templates
- Transmit DICOM data;
- Desktop patient management
- Review images;
- ROI management;
- Web-based patient management

- Open and save of files.

5. Identification of Predicate Device

510(k) Number: K191928
Product Name: AccuContour™

6. Non-Clinical Test Conclusion

The proposed device can contour additional OARs than the predicate device, including:

- Head&Neck: 1) External Auditory Meatus L; 2) External Auditory Meatus R; 3) Middle Ear L-include mastoid; 4) Middle Ear R-include mastoid; 5) Body
- Abdominal &Pelvic: 1) Spleen; 2) Intestinal Tube; 3) Peritoneal Cavity; 4) Femoral Head_Neck L; 5) Femoral Head_Neck R; 6) Body
- Thorax: 1) Humeral Head L; 2) Humeral Head R; 3) Breast L; 4) Breast R; 5) Body

For the same segment organs between proposed device and predicate device, the segmentation performance test was performed on proposed device and predicate device to evaluate the automated segmentation accuracy. The 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. 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.

For the additional segment organs of the proposed device than predicate device, the automatic and manual segmentation was performed on proposed device to evaluate the automated segmentation accuracy. The manual segmentation was generated from the consensus of at least three licensed physicians. The 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. DSC values were calculated. The average DSC of additional segment organs was compared to the average DSC of other segment organs. According to the results, it could be concluded that the DSC of additional segment organs of proposed device was non-inferiority compared with that of other segment organs of proposed device

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological Characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K191928	Remark
Product Code	QKB	QKB	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Class	II	II	Same
Indication for Use	It is used by radiation oncology department to 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 multimodality images and segment (non-contrast) CT images, to generate needed information for treatment planning, treatment evaluation and treatment adaptation.	Different
Label/labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Operation System	Windows	Windows	Same
Segmentation Features			
Algorithm	Deep Learning	Deep Learning	Same
Segmentation of Organ at Risk in the Anatomic Regions	Head & Neck, Thorax, Abdomen &Pelvis	Head & Neck, Thorax, Abdomen &Pelvis	Same
Compatible Modality	Non-Contrast CT	Non-Contrast CT	Same
Compatible Scanner Models	No Limitation on scanner model, DICOM 3.0 compliance required	No Limitation on scanner model, DICOM 3.0 compliance required	Same
Compatible Treatment Planning System	No limitation on TPS model, DICOM 3.0 compliance required	No limitation on TPS model, DICOM 3.0 compliance required	Same
Target Population	Adults Only (greater than 21 years of age)	Any patient type for whom Relevant multimodality images and segment (noncontrast) CT images are available.	Different
Clinical condition the device is intended to diagnose, treat or manage	Limited to patients previously selected for Radiation Therapy. However, RT-Mind-AI can be used for treatment evaluation and treatment adaptation.	Limited to patients previously selected for Radiation Therapy. However, AccuContour can be used for treatment evaluation and treatment adaptation.	Same

Software Architecture	Server based	Cloud and/or Server based	Different
Deployment Feature	Server	Cloud Deployment and Server	Different
Automated workflow	RT-Mind-AI automatically processes input image data	AccuContour automatically processes input image data	Same
Contour visualization and editing feature	RT-Mind-AI provides basic result preview of automatic segmentation results. Manual segment is possible.	AccuContour provides basic result preview of automatic segmentation results. Manual segment is possible.	Same
Segmentation Performance	The segmentation performance was validated using datasets from the USA using three major vendors (GE, Siemens and Phillips). The segmentation accuracy is evaluated using DICE coefficient.	The segmentation performance was validated using datasets from China and the USA using three major vendors (GE, Siemens and Phillips). The segmentation accuracy is evaluated using DICE coefficient.	Different
User Interface – Results Preview (Confirmation)	Basic result preview of automatic segmentation results. Manual segment is possible.	Basic result preview of automatic segmentation results. Manual segment is possible.	Same
User Interface Configuration	Configuration menu	Configuration menu	Same
Human Factors	Design to be used by trained clinicians.	Design to be used by trained clinicians.	Same
Contraindications	None	None	Same

Different - Indication for Use

The Indication for Use of the proposed device is different from that of the predicate device, because the predicate device contains registration and segmentation function, but the proposed device only contains segmentation function. The indication for use of the proposed device is within the range of that of predicate device, therefore, the proposed device will not have new adverse effect.

In addition, the segmentation performance test has been conducted on the proposed device and predicate device. And the test result show that the DSC of proposed device was non-inferiority compared with that of the predicate device

Therefore, the proposed device will not have new adverse effect.

Different - Target Population

The target population is different from that of the predicate device. However, the target population range of the proposed device is within that of the predicate device. In addition, the segmentation performance

test has been conducted on the proposed device and predicate device. And the test result show that the DSC of proposed device was non-inferiority compared with that of the predicate device. Therefore, the proposed device will not have new adverse effect.

Different - Software Architecture
The software architecture of the proposed device is different from that of the predicate device. However, the software architecture used in proposed device is within the range of that of the predicate device. Therefore, the proposed device will not have new adverse effect.

Different - Deployment Feature
The deployment feature of the proposed device is different from that of the predicate device. However, the deployment feature used in proposed device is within the range of that of the predicate device. Therefore, the proposed device will not have new adverse effect.

Different - Segmentation Performance
The datasets used in segmentation performance test for the proposed device is different from that of the predicate device. However, the datasets used in segmentation performance test for the proposed device is from the USA. Therefore, the proposed device will not have new adverse effect.

9. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device K191928.