August 26, 2026

Manteia Technologies Co., Ltd.
Chao Fang
Quality Manager
Unit 3001-3005, No.5 Huizhan North Road
Xiamen City, Fujian Province,
P.R. China

Re: K260733
Trade/Device Name: MRIA Radiation Therapy Information System (MRIA)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: July 30, 2026
Received: July 30, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.	K260733

Please provide the device trade name(s).

MRIA Radiation Therapy Information System (MRIA)

Please provide your Indications for Use below.

MRIA is a radiation therapy information system, mainly for doctors, physicists, technologists and administrators in the radiotherapy department of hospitals to solve the problem of inconvenient information interaction in their positioning, contouring, planning and treatment sessions.
MRIA is not a treatment planning system or a radiation delivery device. It is used only for process progress management and treatment information management for radiotherapy patients.

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

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

Please select the age group(s) for which the device(s) is to be used.

- ☒ Neonates/Newborns (Birth to < 29 days old)
- ☒ Infants (29 days old to < 2 years old)
- ☒ Children (2 years old to < 12 years old)
- ☒ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

510(k) Summary

Traditional 510(k) Submission for MRIA Radiation Therapy Information System

The following information is provided as required by 21 CFR 807.92.

The assign 510(k) Number: K260733

I. SUBMITTER

Manteia Technologies Co., Ltd.
Unit 3001-3005, No.5 Huizhan North Road, Xiamen City, Fujian Province, P.R. China
Establishment Registration Number: 3016686005
Contact Person: Chao Fang
Position: Quality Manager
Email: ra@manteiatech.com
Date of Prepared: 08/24/2026

II. DEVICE

Subject Device/Trade Name: MRIA
Common Name: MRIA Radiation Therapy Information System
Classification Name: accelerator, linear, medical
Classification: II
Product Code: IYE
Regulation Number: 21CFR 892.5050
Review Panel: Radiology

III. PREDICATE DEVICE

Predicate Device: ARIA Radiation Therapy Management System (18.1) (K242463)
Reference Device: MOSAIQ Oncology Information System (K183034)

IV. DEVICE DESCRIPTION

MRIA, defined as a radiation therapy information system, aims to connect the relevant servers of the radiation therapy information system to the hospital's office network and users can access it through the browser of a computer connected to the office network, enabling relevant personnel to manage the process progress and treatment information of radiotherapy patients. Its main functions lie in the following three modules:

- Process Management: Review of radiotherapy treatment plans and medical images, audit radiotherapy charts and schedule CT scans and treatment appointments
- Data Management: manage the transmission, display, output and storage of patient image information and radiotherapy data, supports DICOM 3.0 compliant images (CT, CBCT,

MR, PET-CT, 4DCT) and radiotherapy data (RTStruct, RTPlan, RTDose),develop patient datasets according to different patient types.

- User Management: Creates roles and manages role permissions, configures message templates, and manages department information and hosptial information.

V. INDICATIONS FOR USE

MRIA is a radiation therapy information system, mainly for doctors, physicists, technologists and administrators in the radiotherapy department of hospitals to solve the problem of inconvenient information interaction in their positioning, contouring, planning and treatment sessions.

MRIA is not a treatment planning system or a radiation delivery device. It is used only for process progress management and treatment information management for radiotherapy patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device is MRIA, a radiotherapy information system. The predicate device is ARIA Radiation Therapy Management System (K242463). MOSAIQ Oncology Information System (K183034) is used as a reference device only to provide supporting scientific rationale for certain technical and functional comparisons. The main differences in the subject device compared with the predicate device ARIA (K242463) and the reference device MOSAIQ (K183034) are as follow:

- Indications of Use
- Server Operating System
- RT Treatment Plan Review - The subject device only supports viewing patients' medical plans and does not have any permission to edit or modify them. The predicate device (K242463) have the function of creating and editing treatment plans via customizable templates and can participate in the formulation and adjustment of treatment plans.
- Image Review - Image Review: MRIA only supports image viewing and lacks image-registration algorithms (automatic, manual or fiducial marker matching) available in the predicate ARIA. MRIA provides basic image review without performing image-processing operations.
- Display Patient and plan list -MRIA supports export of process-form data to PDF, patient-list data to Excel, and statistical-chart outputs to PNG and Excel formats. The predicate ARIA supports saving patient data via DICOM or XML storage workflows.
- DICOM RT - This is solely a difference in terminology. In essence, there is universal support for DICOM 3.0-compliant medical images and radiotherapy objects — including RTStruct, RTPlan, and RTDose — for the storage and retrieval of radiotherapy data across both the subject device and the predicate/reference devices.

The detailed comparison of technical parameters is shown in the table below.

ITEM	Subjective Device MRIA	Predicate Device ARIA Radiation Therapy Management System (K242463)	Reference Device MOSAIQ Oncology Information System (K183034)
Regulatory Information			
Regulation No.	21CFR 892.5050	21CFR 892.5050	21CFR 892.5050
Product Code	IYE	IYE	IYE
Class	II	II	II
Indications of Use	MRIA is a radiation therapy information system, mainly for doctors, physicists, technologists and administrators in the radiotherapy department of hospitals to solve the problem of inconvenient information interaction in their positioning, contouring, planning and treatment sessions. MRIA is not a treatment planning system or a radiation delivery device. It is used only for process progress management and treatment information management for radiotherapy patients.	The ARIA Radiation Therapy Management product is a treatment plan and image management application. It enables the authorized user to enter, access, modify, store and archive treatment plan and image data from diagnostic studies, treatment planning, simulation, plan verification and treatment.ARIA Radiation Therapy Management also stores the treatment histories including dose delivered to defined sites and provides tools to verify performed treatments.	MOSAIQ® is an oncology information system used to manage workflows for treatment planning and delivery. It supports information flow among healthcare facility personnel and can be used wherever radiotherapy and/or chemotherapy are prescribed. Users can configure MOSAIQ® for Medical Oncology use, Radiation Oncology use, or the two together. MOSAIQ® is not intended for use in diagnosis. Medical oncology dose calculation functions are designed for use with patients 18 years or older only.
Intended User	Trained radiation oncology personnel	Trained medical professionals	Healthcare facility personnel
Server Operating System	Ubuntu	Windows	Windows

ITEM	Subjective Device MRIA	Predicate Device ARIA Radiation Therapy Management System (K242463)	Reference Device MOSAIQ Oncology Information System (K183034)
Independent Software	YES	YES	YES
Process Management Feature			
RT Treatment Plan Review	YES	YES （The device supports to create and edit treatment plans using customizable templates.）	YES （The device supports to use the Treatment Plan Editor window to view and modify the treatment plan.）
Image Review	YES	YES （The device supports comparison using automatic, manual or fiducial marker matching algorithms.）	YES
RT Chart Auditing	YES	YES	YES
CT/Treatment Appointment	YES	NA	YES
Data Management Feature			
Display Patient and plan list	YES (The device supports to export the treatment process form data in PDF file format; patient list data support EXCEL table export; statistical analysis data chart support to picture png format and EXCEL format export.)	YES (The device supports to save to your preferred storage solution using DICOM or XML format and update patient info when necessary.)	YES
Dataset Management	YES	NA	YES

ITEM	Subjective Device MRIA	Predicate Device ARIA Radiation Therapy Management System (K242463)	Reference Device MOSAIQ Oncology Information System (K183034)
DICOM RT	YES [The device supports DICOM 3.0 compliant images (CT, CBCT, MR, PET-CT, 4DCT) and radiotherapy data (RTStruct, RTPlan, RTDose)]	YES [The device supports DICOM compliant images (MV, kV, CT, CBCT, MR, PET-CT, 4DCT) and radiotherapy data.]	YES (The device supports to store, archive, and retrieve full-fidelity medical images in DICOM format in accordance with standards. These DICOM data include: medical images, RTStruct, RTPlan and RTDose.)
User Management Feature			
Role Authority	YES	YES	YES
Message Center	YES	YES	YES
Departmental Management	YES	YES	YES
Hospital Information	YES	YES	NA

VII. PERFORMANCE DATA

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

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. The software development and maintenance processes conform to IEC 62304: 2006/AMD1: 2015 (Medical device software - Software life cycle processes), as declared in the Declaration of Conformity, and risk management was performed in accordance with ISO 14971. Verification and validation of the software was conducted to ensure that the product meets users' needs and intended use. MRIA passed all software verification and validation tests including unit, integration and system testing.

Cybersecurity Testing

Cybersecurity risk management was performed in accordance with Section 524B of the FD&C Act, and documentation was provided as recommended by FDA' s guidance on the content of premarket submissions for the management of cybersecurity in medical devices. The cybersecurity risk management report and threat model were prepared, and cybersecurity testing was conducted, including penetration testing. All identified cybersecurity risks were mitigated to an acceptable level and the residual risks are considered acceptable.

No animal studies or clinical tests have been included in this pre-market submission.

Use of Consensus Standards

The following list of FDA-recognized, voluntary consensus standards were utilized in the design and evaluation of the subject device's safety and effectiveness.

ISO 14971:2019	Medical devices - Application of risk management to medical devices
IEC 62304:2006+A1:2016	Medical device software - Software life - cycle processes
IEC 62366- 1:2015+A1:2020	Application of usability engineering to medical devices
ISO 20417:2021	Information supplied by the manufacturer of medical devices
ISO 15223- 1:2021	Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied- Part1:General requirements
IEC 61217:2011	Radiotherapy equipment, Coordinates, Movements and Scales
AAMI RT2:2017	Radiation Therapy Readiness Check
IEC 81001-5-1:2021	Health software and health IT systems-Safety, effectiveness and security - Part 5-1: Security-Activities in the product life cycle
ANSI/UL 2900-1:2017	Standard for Software Cybersecurity for Network -

	Connectable Products, Part 1: General Requirements
ANSI/UL 2900-2-1:2017	Software Cybersecurity for Network -Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems

VIII. CONCLUSIONS

MRIA is believed to be substantially equivalent to the predicate device 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 ARIA (K242463).

Therefore, Manteia Technologies Co., Ltd. considers the subject device, MRIA, to be substantially equivalent to the predicate device ARIA (K242463).