May 19, 2025

Vision RT Ltd
Watheq Al-Hakam
Senior Regulatory Affairs Specialist
Dove House, Arcadia Avenue
London, N3 2JU
United Kingdom

Re: K243301
Trade/Device Name: MapRT
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: April 24, 2025
Received: April 24, 2025

Dear Watheq Al-Hakam:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243301

Device Name

MapRT

Indications for Use *(Describe)*

MapRT is indicated for assisting with planning of radiation therapy by:

- Assessing which combinations of gantry/couch angle and isocentre may result in a collision and which are available to potentially enhance the dose distribution; and
- Predicting when a treatment plan might result in a collision between the treatment machine and the patient or support structures

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The information below is provided for modifications to MapRT following the requirements of the Safe Medical Device Act (SMDA) of 1990, and the content is provided in conformance with 21 CFR 807.92.

Submitter's information

Submitter's name:	Watheq Al-Hakam
Company:	Vision RT Ltd.
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Contact person:	Watheq Al-Hakam Senior Regulatory Affairs Specialist
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Email:	regulatory@visionrt.com
Date summary was prepared:	18-Oct-2024

Primary Predicate device information

Device name:	MapRT
Premarket notification:	K231185
Manufacturer:	Vision RT Limited
Common name:	Surface-guided clearance mapping system
Classification:	Class II
Classification name:	Medical charged-particle radiation therapy system
Regulation number:	892.5050

Device information

Trade name:	MapRT
Common name:	Surface-guided clearance mapping system
Classification:	Class II

Classification name:	Medical charged-particle radiation therapy system
Regulation number:	892.5050
Product code:	IYE
Classification panel:	Radiology

Device description

MapRT is used by radiotherapy professionals during the CT simulation and treatment planning stages of radiotherapy for collision avoidance and facilitating dose optimisation.

MapRT uses two lateral wide-field cameras in simulation to deliver a full 3D model of patients and accessories. This model is then used to calculate a clearance map for every couch (x-axis) and gantry (y-axis) angles. Radiotherapy treatment plans can then be imported automatically to check beams, arcs, and the transition clearance.

Indications for use

MapRT is indicated for assisting with planning of radiation therapy by:

- Assessing which combinations of gantry/couch angle and isocentre may result in a collision and which are available to potentially enhance the dose distribution; and
- Predicting when a treatment plan might result in a collision between the treatment machine and the patient or support structures.

Technological characteristics

The substantial equivalence comparison table below provides a comparison of the technological characteristics of MapRT to those of the predicate d
MapRT.

	Predicate device (K231185 MapRT v1.0)	**Subject device (K243301 MapRT v1.2)**	**Comments**
Manufacturer	Vision RT Ltd.	Vision RT Ltd.	Equivalent to the predicate device.
Indications for use	MapRT is indicated for assisting with planning of radiation therapy by: - Assessing which combinations of gantry/couch angle and isocentre may result in a collision and which are available to potentially enhance the dose distribution; and - Predicting when a treatment plan might result in a collision between the treatment machine and the patient or support structures.	MapRT is indicated for assisting with planning of radiation therapy by: - Assessing which combinations of gantry/couch angle and isocentre may result in a collision and which are available to potentially enhance the dose distribution; and - Predicting when a treatment plan might result in a collision between the treatment machine and the patient or support structures.	Equivalent to the predicate device.
Contra-indications	None.	None.	Equivalent to the predicate device.
Intended users	Trained clinically qualified	MapRT is intended to be used	Equivalent to the predicate

	Predicate device (K231185 MapRT v1.0)	Subject device (K243301 MapRT v1.2)	Comments
	radiation oncology personnel.	by radiotherapy professionals.	device.
OTC/Rx	Rx	Rx	Equivalent to the predicate device.
Functionality	Simulates Radiation Treatment Plans to check static and arc beams, and transition clearance in between fields, predict collisions between the gantry and patient, couch and accessories and facilitate dose optimisation. - reconstruction of patient and treatment accessory surfaces acquired during simulation; - modelling the geometry and movement of equipment within the radiotherapy environment to check for collisions in the designed plan; - and facilitating treatment plan optimisation.	Simulates Radiation Treatment Plans to check static and arc beams, and transition clearance in between fields, predict collisions between the gantry and patient, couch and accessories and facilitate dose optimisation. - reconstruction of patient and treatment accessory surfaces acquired during simulation; - modelling the geometry and movement of equipment within the radiotherapy environment to check for collisions in the designed plan; - and facilitating treatment plan optimisation.	Equivalent to the predicate device.

	Predicate device (K231185 MapRT v1.0)	Subject device (K243301 MapRT v1.2)	Comments
Energy used and/or delivered	None - software-only application. The software application does not deliver or depend on energy delivered to or from patients.	None - the software application and couch markers do not deliver or depend on energy delivered to or from patients.	Equivalent to the predicate device.
Design: Graphical User Interface	Contains a Data Visualisation / Graphical User Interface	Contains a Data Visualisation / Graphical User Interface	Minor differences to the predicate device, the changes that have been made are visual only and do not impact the clinical workflow. This minor difference does not affect the safety or effectiveness of the device. MapRT works as intended and sufficient verification & validation testing has been conducted which show the software functions effectively to achieve its intended use.
Design: supported files	Files exported from the Treatment Planning System containing Treatment Plan (including treatment field)	Files exported from the Treatment Planning System containing Treatment Plan (including treatment field)	Equivalent to the predicate device.

	Predicate device (K231185 MapRT v1.0)	Subject device (K243301 MapRT v1.2)	Comments
	parameters.	parameters.	
Design: calculation requirements	Uses local hardware and couch markers.	Uses local hardware and couch markers.	Equivalent to the predicate device.
Design: reporting	Reporting built-in and user has ability to customise.	Reporting built-in and user has ability to customise.	Equivalent to the predicate device.
Pure software	Uses both software and hardware (5x adhesive couch markers).	Uses both software and hardware (5x adhesive couch markers).	Equivalent to the predicate device.
Operating system	Windows.	Windows.	Equivalent to the predicate device.
Input	Treatment data obtained from supporting Treatment Planning System.	Treatment data obtained from supporting Treatment Planning System.	Equivalent to the predicate device.
Simulation details	Simulates the plan and predicts whether any gantry collisions occur with patient or support structures. Calculates gantry clearance by modelling the patient and accessory surfaces acquired during CT simulation, along with pre-loaded models of the couch and gantry created from LiDAR scans or 3D CAD models. Clearance is calculated with an	Simulates the plan and predicts whether any gantry collisions occur with patient or support structures. Calculates gantry clearance by modelling the patient and accessory surfaces acquired during CT simulation, along with pre-loaded models of the couch and gantry created from LiDAR scans or 3D CAD models. Clearance is calculated with an	Equivalent to the predicate device.

	Predicate device (K231185 MapRT v1.0)	Subject device (K243301 MapRT v1.2)	Comments
	accuracy of ± 2cm.	accuracy of ± 2cm.	
Collision check output	MapRT presents a Clearance Map to the user using the couch (x axis) and gantry (y axis) to show collision-free angles and angles resulting in a collision at any given isocentre. MapRT also displays these angles visually using the acquired patient and accessory surfaces and pre-loaded models of the couch and gantry. The user can interact with the Clearance Map to inspect clearance at any couch / gantry angle and isocentre.	MapRT presents a Clearance Map to the user using the couch (x axis) and gantry (y axis) to show collision-free angles and angles resulting in a collision at any given isocentre. MapRT also displays these angles visually using the acquired patient and accessory surfaces and pre-loaded models of the couch and gantry. The user can interact with the Clearance Map to inspect clearance at any couch / gantry angle and isocentre.	Equivalent to the predicate device.
Dose optimisation	MapRT presents a Clearance Map to the user This map displays which couch / gantry angles and isocentres would result in a collision during treatment, and which are available to enhance the dose distribution.	MapRT presents a Clearance Map to the user This map displays which couch / gantry angles and isocentres would result in a collision during treatment, and which are available to enhance the dose distribution.	Equivalent to the predicate device.
Materials	couch/index bar markers:	couch/index bar markers:	Materials used are substantially equivalent to

	Predicate device (K231185 MapRT v1.0)	Subject device (K243301 MapRT v1.2)	Comments
	High-durability paper stickers with permanent adhesive acrylic.	High-tack vinyl markers overlayed with clear matt over-laminating film.	the predicate device. As per Appendix A of Evaluating Substantial Equivalence in Premarket Notifications 510(k), the materials do not impact the technological characteristics of the device. The materials do not have any biocompatibility concerns or introduce any new safety and effectiveness concerns.

Table 1 - Substantial Equivalence table

Performance data

As with the predicate device, no clinical investigations were performed for MapRT. Verification tests were performed to ensure that the module works as intended and pass/fail criteria were used to verify requirements. Validation testing was performed using summative evaluation techniques per 62366-1:2015/A1:2020. Verification and validation testing passed in all test cases.

Conclusion

MapRT is substantially equivalent to the predicate device. The minor technological change to the graphical user interface between MapRT and the predicate device does not raise any questions on the safety and effectiveness of MapRT.

Verification and validation activities have been performed following the same methods as the cleared device. Results of verification and validation activities confirm that the device continues to meet the design specifications and performs as intended. There are no changes to the indications or intended use of the device.