Vision RT Ltd
℅ Jade Dunphy
Regulatory Affairs Manager
Dove House, Arcadia Avenue
London, N3 2JU
UNITED KINGDOM

June 23, 2023

Re: K231185
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 12, 2023
Received: April 26, 2023

Dear Jade Dunphy:

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: 2023.06.23 13:17:25 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
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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)*
K231185

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.

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510(k) Premarket Notification – MapRT

510(k) Summary

The information below is provided for 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.

1. Submitter's information

Submitter's name:	Jade Dunphy
Company:	Vision RT Ltd.
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Contact person:	Jade Dunphy Regulatory Affairs Manager
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Fax:	N/A
Email:	regulatory@visionrt.com
Date summary was prepared:	12-Apr-2023

2. Device information

Trade name:	MapRT
Common name:	Surface-guided clearance mapping system
Classification:	Class II
Classification name:	Accessory to Medical charged-particle radiation therapy system
Regulation number:	892.5050
Product code:	IYE
Classification panel:	Radiology

3. Predicate device information

Predicate device

Device name:	ClearCheck Model RADCC V2
Premarket notification:	K220583
Manufacturer:	Radformation, Inc.

4. Subject device

Name of the device:	MapRT
Device manufacturer:	Vision RT Ltd.
Common name:	Surface-guided clearance mapping system

Device classification:	Class II, 21 CFR 892.5050
Classification name:	Medical charged-particle radiation therapy system
Product code:	IYE
Classification panel:	Radiology

5. Device description

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

MapRT is a system which uses advanced software and couch markers to deliver a full 3D model of the patient and accessories. This model is used to calculate a clearance map for all couch and gantry angles. Plans can be imported to check beams, arcs and transition clearance.

6. 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.

7. Technological characteristics

The substantial equivalence comparison table below provides a comparison of the technological characteristics of MapRT to those of the predicate device, ClearCheck Model RADCC V2.

	Predicate device (ClearCheck Model RADCC V2)	Subject device (MapRT)	Comments
Device name	ClearCheck Model RADCC V2	MapRT	Different name to the predicate device.
Manufacturer	Radformation, Inc.	Vision RT Ltd.	Different manufacturer to the predicate device.
Indications for use	ClearCheck is intended to assist radiation therapy professionals in generating and assessing the quality of radiotherapy treatment plans. ClearCheck is also intended to assist radiation treatment planners in 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.	Minor differences to the predicate device. MapRT is indicated for a subset of the predicate indication. It is not indicated for generating radiotherapy treatment plans. In terms of assessing the quality of radiotherapy treatment plans and predicting potential collisions, the indications are equivalent to the predicate device. This minor difference does not affect the safety or effectiveness of the device. MapRT works as intended. Sufficient performance data has been collated and shows the software functions effectively to achieve its intended use.
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.

	Predicate device (ClearCheck Model RADCC V2)	Subject device (MapRT)	Comments
Intended users	Trained clinically qualified radiation oncology personnel.	MapRT is intended to be used by radiotherapy professionals.	Equivalent to the predicate device.
OTC/Rx	Rx	Rx	Equivalent to the predicate device.
Functionality	Performs dosimetric and plan evaluation for Radiation Treatment Plans. Also simulates the plan and predicts whether gantry collisions occur with patient or support structures.	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.	Minor differences with the predicate device. Dosimetric evaluation is not a function of MapRT. Otherwise, features are equivalent to the predicate device. This minor difference does not affect the safety or effectiveness of the device. MapRT works as intended. Sufficient performance data has been collated and shows the software functions effectively to achieve its intended use.
Design: Graphical User Interface	Contains a Data Visualisation / Graphical User Interface	Contains a Data Visualisation / Graphical User Interface	Equivalent to the predicate device.
Design: supported files	Files/Treatment Planning System API-provided data containing CT, Structure Set, and Treatment Plan (including treatment field) parameters.	Files exported from the Treatment Planning System containing Treatment Plan (including treatment field) parameters.	Equivalent to the predicate device.
Design: calculation requirements	Uses local hardware	Uses local hardware and couch markers	Minor differences with the predicate device. MapRT

	Predicate device (ClearCheck Model RADCC V2)	Subject device (MapRT)	Comments
			uses couch markers as a hardware accessory to assist with calibration. These markers are not intended for contact with the patient or user, except incidental contact. The materials have been assessed for biocompatibility and do not introduce any new safety and effectiveness concerns. Verification and validation testing has been conducted with the couch markers and shows that the addition of these couch markers doesn't pose any safety or effectiveness concerns.
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	Yes	Uses both software and hardware (5x adhesive couch markers)	Minor differences with the predicate device. MapRT is primarily software, however it also uses couch markers uses couch markers as a hardware accessory to assist with calibration. These markers are not intended for contact with the patient or user, except incidental contact. The materials have been

	Predicate device (ClearCheck Model RADCC V2)	Subject device (MapRT)	Comments
			assessed for biocompatibility and do not introduce any new safety and effectiveness concerns. Verification and validation testing has been conducted with the couch markers and shows that the addition of these couch markers doesn't pose any safety or effectiveness concerns.
Operating system	Windows	Windows	Equivalent to the predicate device.
Input	Treatment data, image data and structure set data obtained from supporting Treatment Planning System and Application Programming Interfaces.	Treatment data obtained from supporting Treatment Planning System.	Minor differences with the predicate device. MapRT does not import data from the APIs. There are no safety or effectiveness concerns as there are no risks associated with the APIs.
Simulation details	Simulates the plan and predicts whether any gantry collisions occur with patient or support structures.	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 accuracy of ± 2cm.	Minor differences with the predicate device. Gantry clearance is displayed to the user, who can view treatment deliverability at any given combination of couch / gantry angle and isocentre. Clearance is calculated with an accuracy of ± 2cm. This minor difference does not affect the safety or effectiveness of the device. MapRT works as intended.

	Predicate device (ClearCheck Model RADCC V2)	Subject device (MapRT)	Comments
	Calculates gantry clearance by modelling the linac as a cylinder with a user-configured value for distance between isocentre and the face of the gantry. Collision Check also supports additional applicators: Stereotactic radiosurgery cones (also modelled as a cylinder) and Electron Applicators (modelled as a rectangular prism). ClearCheck also simulates the on-board imaging (OBI) arms as a rectangular prism. User can define a warning distance that adds a margin to the shapes in the simulation.		Sufficient performance data has been collated and shows the software functions effectively to achieve its intended use.
Collision check output	Collisions Check tests thousands of sample points against CT data and patient and couch structures and reports the number of sample points that resulted in a collision. Collision Check also displays these sample point test results with a 3D display and an axial 2D image plan viewer for the user to inspect the results.	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.	Minor differences with the predicate device. The Clearance Map generated by MapRT is interactive, allowing the user to inspect the results at any angle or isocentre. This minor difference does not affect the safety or effectiveness of the device. MapRT works as intended. Sufficient performance data has been collated and shows the software functions effectively to achieve its intended use.

	Predicate device (ClearCheck Model RADCC V2)	Subject device (MapRT)	Comments
Dose optimisation	Collisions Check tests thousands of sample points against CT data and patient and couch structures and reports the number of sample points that resulted in a collision. Collision Check also displays these sample point test results with a 3D display and an axial 2D image plan viewer for the user to inspect the results.	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.	Minor differences with the predicate device. The predicate checks a single plan for collisions and provides binary data on whether or not a collision is predicted. Whereas, the Clearance Map generated by MapRT allows the user to identify all combinations of couch / gantry and isocentre available to enhance the dose distribution. This minor difference does not affect the safety or effectiveness of the device. MapRT works as intended. Sufficient performance data has been collated and shows the software functions effectively to achieve its intended use.

8. 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 IEC 62366-1:2015. Verification and validation testing passed in all test cases.

9. Conclusion

MapRT is substantially equivalent to the predicate device. The technological differences between MapRT and the predicate device does not raise any questions on the safety and effectiveness of MapRT. Verification and validation testing demonstrate that MapRT is safe and effective and performs as well as or better than the predicate device.