Vision RT Ltd.
% Jade Dunphy
Regulatory Affairs Manager
Dove House
Arcadia Avenue
London, N3 2JU
United Kingdom

November 10, 2021

Re: K212583
Trade/Device Name: AlignRT Plus
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: August 13, 2021
Received: August 16, 2021

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,

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)*
K212583

Device Name
AlignRT Plus

Indications for Use *(Describe)*
The AlignRT Plus system is indicated for use to position and monitor patients relative to the prescribed treatment isocentre, and to withhold the beam automatically during radiation delivery.
For cranial treatments, a manual head adjuster is included which can be used in concert with AlignRT Plus to provide fine corrections for pitch, roll and yaw rotations.
AlignRT Plus is also used to track the patient's respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment.
Patient contour data can be extracted and exported from the data acquired for the purpose of treatment planning.
AlignRT Plus can be calibrated directly to the treatment beam isocentre and in turn assists in performing quality assurance on MV, kV imagers, room lasers and the treatment couch.
AlignRT Plus is indicated for use during simulation, setup and stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated.

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 – AlignRT Plus

510(k) Summary

The information below is provided for the modifications to AlignRT following the format of 21 CFR 807.92.

Submitter: Vision RT Ltd.
Dove House
Arcadia Avenue
London, N3 2JU
United Kingdom
Contact Name: Jade Dunphy
Tel: +44 (0)20 8346 4300
Fax: +44 (0)20 8346 4634

Date Summary was prepared: 17 December 2020

PREDICATE DEVICE INFORMATION:

Name of the Device:	AlignRT Plus
Premarket Notification:	K203387
Trade/Proprietary Name:	AlignRT Plus (incorporating AlignRT, GateCT, GateRT), may be branded as OSMS (Optical Surface Monitoring System).
Manufacturer:	Vision RT Limited
Common or Usual Name:	Surface Guided Radio Therapy System (Patient Positioning System – accessory to a linear accelerator)
Device Class:	II
Classification Name:	Accessory to Medical charged-particle radiation therapy accessories, IYE, (per 21 CFR section 892.5050)
Review Panel:	Radiology

SUBJECT (MODIFIED) DEVICE:

Name of the Device:	AlignRT Plus (incorporating AlignRT, GateCT, SimRT, GateRT), may be branded as OSMS (Optical Surface Monitoring System)
Device Manufacturer:	Vision RT Limited
Common or Usual Name:	Surface Guided Radio Therapy System (Patient Positioning System accessory to a linear accelerator)
Device Class:	II
Classification Name:	Accessory to Medical charged-particle radiation therapy accessories, IYE, (per 21 CFR section 892.5050)
Review Panel:	Radiology

510(k) Premarket Notification – AlignRT Plus

Description of Device:

The AlignRT Plus system (K203387) is a combination of the devices AlignRT, GateCT and GateRT.

AlignRT Plus is a video-based three-dimensional (3D) surface imaging system, which is used to image the skin surface of a patient in 3D before and during radiotherapy treatment. The system consists of advanced software, a computer workstation, and one, two or three 3D camera units (each camera unit comprising a stereo pair of sensors to allow 3D surface reconstruction). The system is non-invasive, does not require the use of body markers and produces no ionizing irradiation during the imaging process.

AlignRT Plus is also able to perform both respiratory synchronised CT imaging and treatment delivery. In both instances, the system acquires a gated 3D surface model of the patient. User selected points are then tracked in real time in order to provide gating and position monitoring signals.

Real-time imaging and surface matching of the patient is possible during both setup and the treatment delivery to determine any patient movement. During treatment delivery, AlignRT Plus is also able to withhold the beam automatically, should the patient move outside user-defined tolerances.

Patient contour data may be extracted from surface data acquired by the system and exported for the purpose of treatment planning by radiotherapy professionals.

AlignRT Plus may be calibrated directly to the treatment beam isocentre using an optional custom designed calibration phantom and image processing software. It can analyse MV and kV digital imaging data acquired by other cleared devices. This in turn assists the user in performing quality assurance on MV, kV imagers, room lasers and the treatment couch.

The AlignRT Plus system includes the optional Head Adjuster for cranial treatments to allow for the manual, fine correction of pitch, roll and yaw in the patient's head position.

Precise isocenter calibration and the optional Head Adjuster provide improved frameless Stereotactic Radiosurgery (SRS). This is provided with the brand name "AlignRT SRS module".

The AlignRT Plus system is also provided under the brand OSMS (Optical Surface Monitoring System). This product is identical to AlignRT.

This 510(k) is requested for a modifications to FDA 510(k) cleared product "AlignRT Plus" (K203387).

This 510(k) is to obtain clearance for the following changes to the cleared device:

1. Introduction of new software, SimRT 7.2. This is an updated version of the cleared software, GateCT, with a new user interface similar to the cleared AlignRT 6.2/6.3/6.4 software;
2. Introduction of new camera pods (hardware). These function in the same way as the currently cleared hardware but are aesthetically different and have upgraded capabilities to support future product development;
3. Improve the product's accuracy claim for Source-Surface Distancing (SSD) from <2.0mm to <0.2mm.

510(k) Premarket Notification – AlignRT Plus

Addition of a new medical device software application for patient and accessory identification, SafeID.

Indications for Use:

The AlignRT Plus system is indicated for use to position and monitor patients relative to the prescribed treatment isocentre, and to withhold the beam automatically during radiation delivery.

For cranial treatments, a manual head adjuster is included which can be used in concert with AlignRT Plus to provide fine corrections for pitch, roll and yaw rotations.

AlignRT Plus is also used to track the patient's respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment.

Patient contour data can be extracted and exported from the data acquired for the purpose of treatment planning.

AlignRT Plus can be calibrated directly to the treatment beam isocentre and in turn assists in performing quality assurance on MV, kV imagers, room lasers and the treatment couch.

AlignRT Plus is indicated for use during simulation, setup and stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated.

No changes are made to the intended use and indications for use.

Summary of the Technological Characteristics:

The Substantial Equivalence Comparison Table shown below provides a comparison of the technological characteristics of AlignRT Plus to those of the predicate device:

510(k) Premarket Notification – AlignRT Plus

	PREDICATE DEVICE	MODIFIED DEVICE	COMMENTS
Device name	AlignRT Plus (K203387) Incorporating AlignRT, GateCT, GateRT	AlignRT Plus Incorporating AlignRT, GateCT, SimRT, GateRT	Addition of SimRT v7.2 software.
Manufacturer	Vision RT Ltd	Vision RT Ltd	The manufacturer has not changed.
Indications for Use	The AlignRT Plus system is indicated for use to position and monitor patients relative to the prescribed treatment isocenter, and to withhold the beam automatically during radiation delivery. For cranial treatments, a manual head adjuster is included which can be used in concert with AlignRT Plus to provide fine corrections for pitch, roll and yaw rotations. AlignRT Plus is also used to track the patient's respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment. Patient contour data can be extracted and exported from the data acquired for the purpose of treatment planning. AlignRT Plus can be calibrated directly to the treatment beam isocenter and in turn assists in performing quality assurance on MV, kV imagers, room lasers and the treatment couch.	The AlignRT Plus system is indicated for use to position and monitor patients relative to the prescribed treatment isocenter, and to withhold the beam automatically during radiation delivery. For cranial treatments, a manual head adjuster is included which can be used in concert with AlignRT Plus to provide fine corrections for pitch, roll and yaw rotations. AlignRT Plus is also used to track the patient's respiratory pattern for respiratory synchronized image acquisition, and radiation therapy treatment. Patient contour data can be extracted and exported from the data acquired for the purpose of treatment planning. AlignRT Plus can be calibrated directly to the treatment beam isocenter and in turn assists in performing quality assurance on MV, kV imagers, room lasers and the treatment couch.	The indications for use are the same as those of the previously cleared device.

	PREDICATE DEVICE	MODIFIED DEVICE	COMMENTS
	AlignRT Plus may be used during simulation, setup and stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated.	AlignRT Plus may be used during simulation, setup and stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation is indicated.	
Principles of operation	Video based imaging of 3D skin surface data using surface matching software.	Video based imaging of 3D skin surface data using surface matching software.	The principles of operation are the same as those of the previously cleared device.
Target Population	Any individual (adult or child) undergoing radiotherapy.	Any individual (adult or child) undergoing radiotherapy.	The target population is the same as that of the previously cleared device.
Materials	PC workstation, cables, video cameras. Block Polystyrene (calibration phantom), carbon fibre laminate material (head adjuster).	PC workstation, cables, video cameras. Block Polystyrene (calibration phantom), carbon fibre laminate material (head adjuster).	Although the Horizon camera is manufactured to a different design specification, the materials used are the same as those of the previously cleared device.

510(k) Premarket Notification – AlignRT Plus

	PREDICATE DEVICE	MODIFIED DEVICE	COMMENTS
System Performance and Accuracy	Positioning accuracy: Target registration errors (as measured using calibration phantom) < 1mm (0.5mm) for all couch angles. Respiratory tracking: Tracks respiratory signal from imaged surface data and sends to CT (4D CT) or to Linac or imaging device (gating). Surface displacements can be tracked with RMS errors < 0.5mm over 10 or more breathing cycles.	Positioning accuracy: Target registration errors (as measured using calibration phantom) < 1mm (0.5mm) for all couch angles. Respiratory tracking: Tracks respiratory signal from imaged surface data and sends to CT (4D CT) or to Linac or imaging device (gating). Surface displacements can be tracked with RMS errors < 0.5mm over 10 or more breathing cycles.	The system performance and accuracy have not changed since previous clearances.
Biocompatibility	The AlignRT Plus product requires no direct contact with the patient. The only interactions between the user and the system are with: • the PC (in the control room) or remote workstation (in the vault), • the Remote Control (in the vault), • the Real Time Coach (RTC) (in the vault), or • the Head Adjuster (in the vault). • Calibration plate (in the vault) • Calibration cube (in the vault) • Calibration levelling plate (in the vault)	The AlignRT Plus product requires no direct contact with the patient. The only interactions between the user and the system are with: • the PC (in the control room) or remote workstation (in the vault), • the Remote Control (in the vault), • the Real Time Coach (RTC) (in the vault), or • the Head Adjuster (in the vault). • Calibration plate (in the vault) • Calibration cube (in the vault) • Calibration levelling plate (in the vault)	Although the Horizon camera is manufactured to a different design specification, the materials used are the same as those of the previously cleared device.

	PREDICATE DEVICE	MODIFIED DEVICE	COMMENTS
	The materials of the devices (which are commonly used in light-industrial, commercial and home use) and that the application only involves intermittent external contact with intact skin.	The materials of the devices (which are commonly used in light-industrial, commercial and home use) and that the application only involves intermittent external contact with intact skin.	
Mechanical Safety	Cameras are ceiling mounted and do not contact patient or user. The InBore camera solution is fixed to the inside of the bore-based linac. Head adjuster is clamped to the treatment couch through universal base plate.	Cameras are ceiling mounted and do not contact patient or user. The InBore camera solution is fixed to the inside of the bore-based linac. Head adjuster is clamped to the treatment couch through universal base plate.	The mechanical safety of the device is the same as that of the previously cleared device.
Anatomical treatment sites	Entire body surface.	Entire body surface.	The anatomical treatment sites of the device are the same as those of the previously cleared device.
Human factors	Imaging process is fully automatic as is estimation of new couch position; 3D visual display provided to show any discrepancy in patient position. For respiratory tracking, user selects region of interest or tracking point(s) during first session. These are detected automatically during subsequent sessions. For cranial treatments, a manual head adjuster may be used by turning designated dials to provide fine corrections for pitch, yaw and roll rotations in concert with real time visual feedback provided to the user by AlignRT Plus.	Imaging process is fully automatic as is estimation of new couch position; 3D visual display provided to show any discrepancy in patient position. For respiratory tracking, user selects region of interest or tracking point(s) during first session. These are detected automatically during subsequent sessions. For cranial treatments, a manual head adjuster may be used by turning designated dials to provide fine corrections for pitch, yaw and roll rotations in concert with real time visual feedback provided to the user by AlignRT Plus.	The human factors are the same as that of the previously cleared device.

	PREDICATE DEVICE	MODIFIED DEVICE	COMMENTS
	There is an extra non-clinical workflow for the InBore camera. A customer must remove the camera in order to service the bore-based linear accelerator.	There is an extra non-clinical workflow for the InBore camera. A customer must remove the camera in order to service the bore-based linear accelerator.	
Optical pattern	Optical (near infra-red) pattern is projected to patient.	Optical (near infra-red) pattern is projected to patient.	The optical pattern of the device is the same as that of the previously cleared device.
Compatibility with the environment and other devices	For use in hospital and clinic environments.	For use in hospital and clinic environments.	The compatibility with the environment is the same as that of the previously cleared device.
General Electrical safety standards	IEC 60601-1 compliant.	IEC 60601-1 compliant.	The modified device has been tested and continues to comply to IEC 60601-1.
EMC standards	IEC 60601-1-2 compliant.	IEC 60601-1-2 compliant.	The modified device has been tested and continues to comply to IEC 60601-1-2: 2014 (4th Ed.).
Size	The camera (key part of the system) has the following dimensions: Cameras (each) – 470 x 220 x 70 – 4.5kg InBore optional camera accessory - Ring 499mm diameter (plus 1mm protrusions) x 177mm wide (max) – 3.2kg	The camera (key part of the system) has the following dimensions: HD Cameras (each) – 470 x 220 x 70 – 4.5kg Horizon cameras (each) – 480 x 140 x 127 – 2.75kg InBore optional camera accessory - Ring 499mm diameter (plus 1mm protrusions) x 177mm wide (max) – 3.2kg	The new Horizon camera is slightly different in size, but lighter in weight to that of the previously cleared cameras.

510(k) Premarket Notification – AlignRT Plus

	PREDICATE DEVICE	MODIFIED DEVICE	COMMENTS
Packaging	The system is packaged in a variety of boxes and then packaged within palletised crate.	The system is packaged in a variety of boxes and then packaged within palletised crate.	The packaging of the device is the same as that of the previously cleared device.
Environmental range	AlignRT Plus is intended for use at altitudes below 2000m (6,561ft). The operating temperature is +16°C to +30°C (60.8° to 86° Fahrenheit). The shipping and storage conditions are -20°C to +50°C (-4° to 122° Fahrenheit).	AlignRT Plus is intended for use at altitudes below 3000m (9,842ft). The operating temperature is +16°C to +30°C (60.8° to 86° Fahrenheit). The shipping and storage conditions are -20°C to +50°C (-4° to 122° Fahrenheit).	The device is a solid-state product and is not affected by altitude. The modified device is substantially equivalent to its predicate device.
Workstation Operating System	Windows 10	Windows 10	No change to operating system.
Number of cameras	1-3 Optional InBore camera	1-3 Optional InBore camera	The number of cameras used are the same as those of the previously cleared device.
Power requirements	110-230V 50/60Hz	110-230V 50/60Hz	The power requirements of the device are the same as those of the previously cleared device.
Network requirements	10BaseT internet connection behind a local firewall.	10BaseT internet connection behind a local firewall.	The network requirements of the device are the same as those of the previously cleared device.
Service provision	All service to be performed by swap-out and return-to-base by Vision RT engineers. Remote support provided by Vision RT engineers through secure remote internet software.	All service to be performed by swap-out and return-to-base by Vision RT engineers. Remote support provided by Vision RT engineers through secure remote internet software.	The service approach of the device is the same as that of the previously cleared device.

Conclusion

The proposed changes are made by the legal manufacturer and submitted by the legal manufacturer authorized to market the existing device (AlignRT Plus). The changes made in subject device were tested using the same test method and acceptance criteria as the predicate device and the subject device is substantially equivalent to the predicate device. The verification and/or validation demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device. The conclusion is based upon the devices' intended use, indications for use, fundamental technological characteristics, principle of operation and performance specifications.