Vision RT Ltd
% Chelsey Ludlow
Regulatory Affairs Specialist
Dove House, Arcadia Avenue
London, N3 2JU
UNITED KINGDOM

March 29, 2024

Re: K233622
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: November 10, 2023
Received: November 13, 2023

Dear Chelsey Ludlow:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233622

Device Name
AlignRT Plus

Indications for Use *(Describe)*
The AlignRT Plus system is indicated for:
• Tracking respiratory motion throughout the simulation process to facilitate subsequent 4DCT reconstruction and coaching the patient in breathing techniques required for Deep-Inspiration Breath Hold (DIBH).
• Verification of patient identity for their radiation treatment session.
• Positioning and monitoring of patients during radiation delivery, relative to the setup isocenter and/or the prescribed treatment isocenter.
• Withholding the beam automatically during radiation delivery, as well as gating the beam based on the patient's respiratory motion.
• Performing quality assurance on MV, kV imagers, room lasers, and the treatment couch.
• Visualizing the Cherenkov signal associated with the radiation beam on entry and exit from the patient.
• Passing and receiving information to/from other systems associated with the radiotherapy treatment.

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 7.3

510(k) Summary

The information below is provided for modifications to AlignRT Plus 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:	Chelsey Ludlow
Company:	Vision RT Ltd.
Address:	Dove House Arcadia Avenue London, N3 2JU United Kingdom
Contact person:	Chelsey Ludlow Regulatory Affairs Specialist
Phone:	+44 (0)20 8346 4300
Fax:	N/A
Email:	regulatory@visionrt.com
Date summary was prepared:	10-Nov-2023

Primary Predicate device information

Device name:	AlignRT Plus (incorporating AlignRT, AlignRT InBore, AlignRT Offline, GateCT, SimRT, GateRT)
Premarket notification:	K212583
Manufacturer:	Vision RT Limited
Common name:	Surface Guided Radio Therapy System (Patient Positioning System – accessory to a linear accelerator)
Classification:	Class II
Classification name:	Accessory to Medical charged-particle radiation therapy system
Regulation number:	892.5050

Reference device information

Device name:	BeamSite
Premarket notification:	K212606
Manufacturer:	DoseOptics LLC
Common name:	Radiotherapy visualization system
Classification:	Class II

510(k) Premarket Notification – AlignRT Plus 7.3

Classification name:	Medical charged-particle radiation therapy system
Regulation number:	892.5050

Device information

Trade name:	AlignRT Plus (incorporating AlignRT, AlignRT InBore, DoseRT, GateCT, GateRT, SimRT)
Common name:	Surface Guided Radio Therapy System (Patient Positioning System – accessory to a linear accelerator)
Classification:	Class II
Classification name:	Accessory to Medical charged-particle radiation therapy system
Regulation number:	892.5050
Product code:	IYE
Classification panel:	Radiology

Device description

The AlignRT Plus system (K212583) is a combination of the devices AlignRT, AlignRT InBore, AlignRT Offline, DoseRT, GateCT, GateRT and SimRT.

AlignRT Plus is a video-based three-dimensional (3D) surface imaging system used to monitor the patient's position in 3D before and during radiotherapy treatment. During each treatment session the patient's position is compared to the reference surface and offsets are displayed to the user. The system can be used to track patients' motion during tumour localization in the CT scanner in order to facilitate subsequent 4D CT reconstruction. The system can be used to track the breath hold level consistency throughout the simulation process. The system can also be used to track patient motion during treatment delivery for radiation therapy procedures and hold the beam when the patient is not in position. Use of optional accessories allows the user to:

- monitor the patient's position inside bore-based linacs; and/or
- to view the Cherenkov light emitted by the radiation beam as it enters and exits the patient's skin; and/or
- verify the patient's identity.

The system is non-invasive, does not require the use of body markers and produces no irradiation during the imaging process. The system mainly consists of advanced software, 3D cameras (≤6 cameras) and calibration tools. Each camera pod monitoring the patient's position will, however, project a pattern on the patient to acquire a 3D image of the patient.

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

1. Introduction of new software, version 7.3. This is an updated version of the existing cleared software, to support the:
    a. New Cherenkov imaging feature, called DoseRT.
    b. Updated respiratory gating feature, called Respiratory Module.

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510(k) Premarket Notification – AlignRT Plus 7.3

2. Introduction of new hardware:
    a. DoseRT camera to enable Cherenkov imaging.
3. Update to indications for use to include the new Cherenkov imaging feature and clarify existing indications.

Throughout this submission, the device will be referred to as AlignRT Plus as the family name for all configurations. No changes have been made to the currently cleared GateCT, GateRT and SimRT configurations.

Indications for use

The AlignRT Plus system is indicated for:

- Tracking respiratory motion throughout the simulation process to facilitate subsequent 4DCT reconstruction and coaching the patient in breathing techniques required for Deep-Inspiration Breath Hold (DIBH).
- Verification of patient identity for their radiation treatment session.
- Positioning and monitoring of patients during radiation delivery, relative to the setup isocenter and/or the prescribed treatment isocenter.
- Withholding the beam automatically during radiation delivery, as well as gating the beam based on the patient's respiratory motion.
- Performing quality assurance on MV, kV imagers, room lasers, and the treatment couch.
- Visualizing the Cherenkov signal associated with the radiation beam on entry and exit from the patient.
- Passing and receiving information to/from other systems associated with the radiotherapy treatment.

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510(k) Premarket Notification – AlignRT Plus 7.3

Primary Predicate and subject device technological characteristics

The features of AlignRT Plus 7.3 are substantially equivalent to the predicate device, AlignRT Plus (K212583), as discussed in the table below:

Technological characteristics	Primary Predicate device (AlignRT Plus, K212583)	Subject device (AlignRT Plus 7.3)	Comments
Manufacturer	Vision RT Ltd	Vision RT Ltd	The manufacturer remains the same as that of the predicate device.
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: • Tracking respiratory motion throughout the simulation process to facilitate subsequent 4DCT reconstruction and coaching the patient in breathing techniques required for Deep-Inspiration Breath Hold (DIBH). • Verification of patient identity for their radiation treatment session. • Positioning and monitoring of patients during radiation delivery, relative to the setup isocenter and/or the prescribed treatment isocenter. • Withholding the beam automatically during radiation delivery, as well as gating the beam based on the patient's respiratory motion. • Performing quality assurance on MV, kV imagers, room lasers, and the treatment couch. • Visualizing the Cherenkov signal associated with the radiation beam	The subject device indications for use have been updated to include visualization of the Cherenkov signal, verification of the patient's identity prior to radiation treatment and to clarify the existing indications. The addition of Cherenkov imaging and verification of the patient's identity and the clarification of the cleared indications does not affect the safety or effectiveness of the device. AlignRT Plus works as intended. Sufficient performance data has been collated and shows the device functions effectively to achieve its intended use.

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510(k) Premarket Notification – AlignRT Plus 7.3

Technological characteristics	Primary Predicate device (AlignRT Plus, K212583)	Subject device (AlignRT Plus 7.3)	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.	on entry and exit from the patient. • Passing and receiving information to/from other systems associated with the radiotherapy treatment.	
Product code	IYE	IYE	Equivalent to the predicate device.
Device Classification	Class II	Class II	Equivalent to the predicate device.
Classification Name	Accessory to Medical charged-particle radiation therapy accessories	Accessory to Medical charged-particle radiation therapy accessories	Equivalent to the predicate device.
Regulation Number	21 CFR 892.5050	21 CFR 892.5050	Equivalent to the predicate device.
Contra-indications	None known.	None known.	Equivalent to the predicate device.
Intended users	Trained clinically qualified radiation oncology personnel.	Trained clinically qualified radiation oncology personnel.	Equivalent to the predicate device.
OTC/Rx	Rx (Prescription)	Rx (Prescription)	Equivalent to the predicate device.
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.	Equivalent to the predicate device.
Target Population	Any individual (adult or child) undergoing radiotherapy.	Any individual (adult or child undergoing radiotherapy).	Equivalent to the predicate device.

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510(k) Premarket Notification – AlignRT Plus 7.3

Technological characteristics	Primary Predicate device (AlignRT Plus, K212583)	Subject device (AlignRT Plus 7.3)	Comments
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). Anodised aluminium and polyester powder coating (DoseRT camera casing). ABS plastic (DoseRT reference board).	The component materials in the subject device are identical to the primary predicate. The introduction of the new components (DoseRT camera casing and DoseRT reference board) and materials have not been evaluated for biocompatibility as they do not come in contact with the patient, nor effect patient safety.
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). The relative respiratory position within respiratory cycles is calculated to an accuracy of ≤0.5mm with a confidence level of ≥95%. The location of the radiation dose on the patient surface during treatment can be visualized using the Cherenkov Effect for treatment at treatment beam energies of ≥6MV and ≤18MV and at treatment beam delivery rates of between ≥100MU/Min and ≤2400MU/Min.	As a result of the updated features, such as the visualization of the Cherenkov signal and respiratory tracking associated with the Respiratory Module software module, the subject's performance, and accuracy differ slightly from the predicate device. In support of the substantial equivalence determination, the validation met the predetermined specifications and acceptance criteria. The performance data demonstrate that the device is as safe and effective as the predicate devices

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510(k) Premarket Notification – AlignRT Plus 7.3

Technological characteristics	Primary Predicate device (AlignRT Plus, K212583)	Subject device (AlignRT Plus 7.3)	Comments
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 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 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) • DoseRT reference board (in the vault) 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.	Biocompatibility tests conducted on the predicate device can be applied to AlignRT Plus 7.3 since the surface contacting components and materials are the same except for the reference board. No additional testing was required since the reference board does not contact patients. These differences do not raise new or different concerns of safety and effectiveness.
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.	Equivalent to the predicate device.
Anatomical treatment sites	Entire body surface.	Entire body surface.	Equivalent to the predicate device.
Human factors	Imaging process is fully automatic as is estimation of new couch position; 3D	Imaging process is fully automatic as is estimation of new couch position; 3D	The subject device continues to meet FDA guidance on “Applying Human Factors and

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510(k) Premarket Notification – AlignRT Plus 7.3

Technological characteristics	Primary Predicate device (AlignRT Plus, K212583)	Subject device (AlignRT Plus 7.3)	Comments
	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.	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.	Usability Engineering to Medical Devices" and IEC 62366-1: 2015 Medical Devices-Part 1: Application of Usability Engineering to Medical Devices. This is equivalent to the predicate device.
Optical pattern	Optical (near infra-red) pattern is projected to patient.	Optical (near infra-red) pattern is projected to patient.	Equivalent to the predicate device.
Compatibility with the environment and other devices	For use in hospital and clinic environments.	For use in hospital and clinic environments.	Equivalent to the predicate device.
General Electrical safety standards	IEC 60601-1 compliant.	IEC 60601-1 compliant.	Equivalent to the predicate device.
EMC standards	IEC 60601-1-2 compliant.	IEC 60601-1-2 compliant.	Equivalent to the predicate device.
Size	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	The camera (key part of the system) has the following dimensions: HD Cameras (each) – 470 x 220 x 70 – 4.5kg	DoseRT cameras are slightly different in size and lighter than the predicate device cameras. The existing cleared cameras in the primary predicate device have not changed in this submission.

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510(k) Premarket Notification – AlignRT Plus 7.3

Technological characteristics	Primary Predicate device (AlignRT Plus, K212583)	Subject device (AlignRT Plus 7.3)	Comments
	InBore optional camera accessory - Ring 499mm diameter (plus 1mm protrusions) x 177mm wide (max) – 3.2kg	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 DoseRT optional camera has the following dimensions (including the front lens): Length: 230mm ± 10mm Width: 76 ± 10mm Height: 83mm ± 10mm Weight: 1500 grams ± 100 grams (including the front lens)	The size of the primary predicate device is substantially equivalent to that of the subject device. The difference in size and weight does not affect the safety or effectiveness of the device.
Workstation Operating System	Windows 10	Windows 10	Equivalent to the predicate device.
Number of cameras	1-3 Optional InBore camera	1-3 Optional InBore camera Up to three optional DoseRT cameras.	Up to three DoseRT cameras can be used depending on the configuration required by the customer. The existing cleared number of cameras in the primary predicate device have not changed in this submission. The number of cameras used are substantially equivalent to the predicate device. The introduction of DoseRT cameras does not affect the safety or effectiveness of the device. Sufficient performance data has been collated and

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510(k) Premarket Notification – AlignRT Plus 7.3

Technological characteristics	Primary Predicate device (AlignRT Plus, K212583)	Subject device (AlignRT Plus 7.3)	Comments
			shows the device functions effectively to achieve its intended use.
Power requirements	110-230V 50/60Hz	110-230V 50/60Hz	Equivalent to the predicate device.
Network requirements	10BaseT internet connection behind a local firewall.	10BaseT internet connection behind a local firewall.	Equivalent to the predicate 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.	Equivalent to the predicate device.

Table 1 – Primary Predicate and subject device comparison

510(k) Premarket Notification – AlignRT Plus 7.3

Reference and subject device technological characteristics

This table details the aspects of the Subject device which cannot be accounted for by the primary predicate device, AlignRT Plus (K212583). The subject device includes amended features such as Dose RT cameras and reference board, and introduction of Cherenkov image visualization. To account for the additional features, Beam Site (K212606) is chosen as the reference device. The table below demonstrates how the DoseRT camera and supporting hardware is exactly the same as the existing cleared reference device.

Technological characteristics	Reference device (BeamSite, K212606)	Subject device (AlignRT Plus 7.3)
Manufacturer	DoseOptics LLC	Vision RT Ltd
Product code	IYE	IYE
Device Classification	Class II	Class II
Classification Name	Medical Charged Particle Radiation Therapy System	Accessory to Medical charged-particle radiation therapy accessories
Regulation Number	892.5050	892.5050
Type of use	Prescription (Rx)	Rx
Indications for Use	The BeamSite System is intended to be used only with photon external beam radiotherapy during treatment to acquire and visualize the shape of the treatment radiation beam relative to surface anatomical landmarks on the patient, anywhere in the body where radiation treatment is indicated. BeamSite is used by radiotherapy professionals in appropriate hospital and freestanding radiation therapy environments.	The AlignRT Plus system is indicated for: • Tracking respiratory motion throughout the simulation process to facilitate subsequent 4DCT reconstruction and coaching the patient in breathing techniques required for Deep-Inspiration Breath Hold (DIBH). • Verification of patient identity for their radiation treatment session. • Positioning and monitoring of patients during radiation delivery, relative to the setup isocenter and/or the prescribed treatment isocenter. • Withholding the beam automatically during radiation delivery, as well as gating the beam based on the patient's respiratory motion. • Performing quality assurance on MV, kV imagers, room

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510(k) Premarket Notification – AlignRT Plus 7.3

Technological characteristics	Reference device (BeamSite, K212606)	Subject device (AlignRT Plus 7.3)
		lasers, and the treatment couch. • Visualizing the Cherenkov signal associated with the radiation beam on entry and exit from the patient. • Passing and receiving information to/from other systems associated with the radiotherapy treatment.
Biocompatibility	No contact with patient or clinical staff in the treatment room.	The AlignRT Plus product requires no direct contact with the patient. The only interactions between the user and the system are with: • DoseRT reference board (in the vault) 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.
Imaging visualisation	BeamSite captures images of Cherenkov light emitted from the patient's skin during radiotherapy to provide an optical map of the treatment beam on the patient.	The AlignRT Plus system can be used to visualize the Cherenkov signal associated with the radiation beam on entry and exit from the patient.

Table 2 – Reference and subject device technological characteristics

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510(k) Premarket Notification – AlignRT Plus 7.3

Performance data

As with the predicate device, no clinical investigations were performed for AlignRT Plus 7.3. 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.

Conclusion

AlignRT Plus 7.3 is substantially equivalent to the predicate device. The technological differences between AlignRT Plus 7.3 and the predicate device does not raise any questions on the safety and effectiveness. Verification and validation testing demonstrate that AlignRT Plus 7.3 is as safe and effective and performs as well as or better than the predicate device.