March 18, 2026

Vision RT Ltd
Chelsey Moore
Regulatory Affairs Specialist
Dove House, Arcadia Avenue
London, N3 2JU
United Kingdom

Re: K253012
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: February 18, 2026
Received: February 18, 2026

Dear Chelsey Moore:

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

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.

510(k) Number *(if known)*
K253012

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) Summary
K253012

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 Moore
Company:	Vision RT Ltd.
Address:	Dove House Arcadia Avenue London, N3 2JU United Kingdom
Contact person:	Chelsey Moore Regulatory Affairs Specialist
Phone:	+44 (0)20 8346 4300
Fax:	N/A
Email:	regulatory@visionrt.com
Date summary was prepared:	9/19/2025

Primary Predicate device information

Device name:	AlignRT Plus
Premarket notification:	K233622
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:	AlignRT Plus
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

The AlignRT Plus system (K233622) is a combination of the devices AlignRT, AlignRT InBore, AlignRT Offline, AlignRT PDW, 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.

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 with the radiotherapy treatment.

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

New features:

- Beam Guide feature - Introduced to visually assist clinical staff during beam setup and treatment by providing visual guidance that supports positional accuracy during patient alignment.
- Automated ROI Selection (Auto ROI) feature - Introduced to support workflow efficiency by identifying target surface regions for tracking, reducing operator-dependent variability in region selection.

In line with the FDA's guidance on full disclosure, there are also minor changes contained in AlignRT Plus 8.1 which have been evaluated as not meeting the threshold for clearance under the 510(k) programme individually.

Non-significant changes

Software updates:

- Migration to .NET 8 framework
- Advanced Camera Optimisation (ACO) replacement
- Windows 11 compatibility
- Cybersecurity enhancements

Data Integrity & Compatibility

- Updated backwards compatibility
- Surface Data Retention following treatment interruptions
- Data Migration tools
- USB/Cat 6a hardware updates
- Addition of RTC Mk3 optional accessory
- DoseRT Bolt-On configuration
- Bug fixes
- Single patient name entry workflow
- Update to the Elekta Integrated Gating interface

Primary predicate and subject device technological characteristics

The substantial equivalence comparison table below provides a comparison of the technological characteristics of AlignRT Plus 8.1 to those of the predicate device, AlignRT Plus 7.3.

Technological characteristics	Predicate device (K233622 AlignRT Plus 7.3)	Subject device (AlignRT Plus 8.1)	Comments
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,	"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,	In accordance with 21 CFR § 807.92(a)(5), no changes have been made to the intended use or indications for use of the device. The subject device maintains the same indications for use as the predicate. Therefore, the indications for use do not raise new questions of safety or effectiveness. This continuity in intended use supports the conclusion that the subject device is substantially equivalent to the predicate device in safety and effectiveness.

	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 with the radiotherapy treatment.	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 with the radiotherapy treatment.	
Auto-ROI	Not available. Workflow for AlignRT Plus 7.3 is manual ROI selection by the clinician.	New feature, Auto-ROI provides predefined templates for standard treatment sites. The clinician can review, modify, and confirm.	The Auto-ROI feature adds automated ROI template generation while maintaining clinician review and confirmation. This modification does not change the device's intended use, consistent with 21 CFR § 807.92(a)(5). Verification and non-clinical bench testing to well-established design control methods confirms that Auto-ROI operates as intended. In accordance with 21 CFR § 807.92(a)(6), Auto-ROI does not raise new questions of safety or effectiveness. Risk assessment and usability evaluation were conducted using established methods, and no safety or effectiveness issues were identified. This consistency in safety and effectiveness

			supports the conclusion that the subject device is substantially equivalent to the legally marketed predicate device.
Beam Guide	Not available. Workflow for AlignRT Plus 7.3 is to follow the standard of care whereby clinicians rely on the linear accelerator's light field projection to visualize the area where radiation will be delivered.	Beam Guide displays the intended radiation field and beam outline on-screen during setup and treatment phases to support alignment assessment. It does not control or deliver radiation.	Beam Guide provides an on-screen visualisation of the intended radiation field and beam outline to support patient setup. It does not control or deliver radiation and does not alter the device's intended use, consistent with 21 CFR § 807.92(a)(5). Verification and non-clinical bench testing to well-established design control methods confirms that Beam Guide operates as intended. In accordance with 21 CFR § 807.92(a)(6), Beam Guide does not raise new questions of safety or effectiveness. Risk assessment and usability evaluation were conducted using established methods, and no safety or effectiveness issues were identified. This consistency in safety and effectiveness supports the conclusion that the subject device is substantially equivalent to the legally marketed 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.	The subject device operates using the same principles of operation as the predicate device, namely, video-based imaging of three-dimensional skin surface data using surface matching software. This technology enables tracking and monitoring of patient positioning by capturing and analysing surfaces to ensure accurate alignment during radiotherapy. In accordance with 21 CFR § 807.92(a)(6), no changes have been made to the core principles of operation. As such, the method by which the device achieves its intended use remains unchanged. This consistency in operational principles supports the conclusion that the subject device does not introduce new questions of safety or effectiveness and is therefore substantially equivalent to the legally marketed predicate device.
System Performance and Accuracy	Positioning accuracy: Target registration errors (as measured	Positioning accuracy: Target registration errors (as measured	The system performance and accuracy of the subject device

	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.	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.	are identical to those of the predicate device. In accordance with 21 CFR § 807.92(a)(6), the subject device continues to meet the same performance specifications. These unchanged performance claims confirm that the device performs to the same standard as the predicate and does not introduce new questions of safety or effectiveness. This consistency in performance and accuracy supports the conclusion that the subject device is substantially equivalent to the legally marketed predicate 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	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	The subject device uses the same user interaction approach as the predicate device. It provides a three-dimensional visual display to help clinical staff identify any differences in patient positioning. For respiratory

	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.	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.	tracking, the user verifies the relevant area of the body to monitor, just as they would with the predicate device. In accordance with 21 CFR § 807.92(a)(5), there have been no significant changes to the user interface, workflow or system controls that would affect ease of use. The device continues to offer a familiar and efficient experience for trained clinical users. This consistency in human factors supports the conclusion that the subject device does not raise new questions of safety or effectiveness and is therefore substantially equivalent to the legally marketed predicate device.
General Electrical safety standards	IEC 60601-1 compliant.	IEC 60601-1 compliant.	As part of the performance evaluation required under 21 CFR § 807.92(a)(6), the subject device was tested for electrical safety in accordance with IEC 60601-1 Edition 3.2. This testing was conducted by an accredited third-party laboratory and demonstrated compliance with the updated standard, which reflects the most current FDA-

			recognised consensus standard requirements for basic safety and essential performance of medical electrical equipment. This testing supports substantial equivalence by confirming that the subject device meets the same safety requirements as the predicate device, which was previously evaluated under an earlier edition. The update to Edition 3.2 does not represent a change in intended use or technological characteristics, nor does alter the device's performance. The subject device continues to operate within the same clinical environment and under the same use conditions as the predicate. In accordance with 21 CFR § 807.92(a)(5) the intended use of the subject device remains unchanged. Per § 807.92(b)(2), the testing related to electrical safety is equivalent, and the updated testing methodology is consistent with current state of the art expectations. In accordance with §

			807.92(b)(3), the conclusions drawn from the testing demonstrates that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device. Therefore, the subject device does not raise new questions of safety or effectiveness and is substantially equivalent.
EMC standards	IEC 60601-1-2 compliant.	IEC 60601-1-2 compliant.	The subject device was tested for electromagnetic compatibility (EMC) in accordance with IEC 60601-1-2 Edition 4.1, updating the version used for the predicate device. Testing of applicable hardware confirmed full compliance with this FDA-recognised consensus standard. This update reflects a change in testing methodology, not in intended use or technological characteristics, as defined under 21 CFR § 807.92(b)(1-2). No clinical testing was required, and no performance changes were introduced. As permitted under § 807.92(b)(3), the revised EMC testing supports the conclusion that the subject device is as safe and effective as

			the predicate. Therefore, in accordance with 21 CFR § 807.92(a)(6), the subject device is substantially equivalent.
Workstation Operating System	Windows 10	Windows 10 and Windows 11	The subject device has been validated for use on both Windows 10 and Windows 11 operating systems. While the predicate device was tested only on Windows 10, the subject device underwent bench testing on Windows 11 to confirm full functional compatibility. In accordance with § 807.92(b)(2), the technological characteristics of the system are substantially equivalent, and the updated operating system support represents a permissible difference in implementation.

Performance data

Consistent with the predicate device, no clinical investigations were required or conducted for the subject device, AlignRT Plus. As part of the performance evaluation required under 21 CFR § 807.92(a)(6), performance bench testing was conducted to confirm that the subject device performs as intended. Test reports conclude that the device performs as intended.

AlignRT Plus v8.1.1 has undergone formal hardware and software verification and validation testing; and it demonstrates the device performance as intended.

Testing was performed according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System Standard, and ISO 14971 Risk Management Standard.

Testing of AlignRT Plus v8.1.1 evaluated the system accuracy of patient positioning and treatment-workflow behavior associated with the use of the Beam Guide and Auto ROI functionality in a clinical environment, to ensure it could be utilized effectively, supporting the required clinical workflows and addressing user needs.

It was validated that the Beam Guide UI can be controlled correctly, that various combinations of single and multiple beams could be selected and that plans could be imported and viewed appropriately. The product consistently achieved expected results, demonstrating functional readiness.

Speed and latency performance measures in AlignRT Plus were verified on production equivalent systems, to ensure there was no degradation in performance, whilst the Beam Guide was functional.

For Auto ROI it was validated that the correct ROI was automatically created for the specified treatment protocol, that the ROI can be modified as required at appropriate times during the treatment workflow and a manual ROI could be drawn if needed.

Across all scenarios, AlignRT v8.1.1 met its performance specifications, with patient-positioning accuracy, workflow execution, and safety-critical behaviors consistently achieving expected results and demonstrating full functional readiness.

Software testing

As part of the performance evaluation required under 21 CFR § 807.92(a)(6), software verification testing was conducted in line with ANSI/AAMI/IEC 62304:2006/A1:2016 to confirm that the subject device performs as intended. Defined pass/fail criteria were used to assess compliance with specified safety and effectiveness requirements. Testing was performed in accordance with FDA recognised guidance “Guidance for the Content

of Premarket Submissions for Software Contained in Medical Devices[1]". All test cases passed, demonstrating consistent performance and confirming that the software operates as intended across supported configurations. No new performance concerns were identified.

EMC and electrical safety testing

In addition, as part of the performance evaluation required under 21 CFR § 807.92 (a)(6), the subject device underwent testing for electromagnetic compatibility (EMC) and electrical safety. EMC testing was conducted in accordance with IEC 60601-1-2 Edition 4.1, and electrical safety testing followed IEC 60601-1 Edition 3.2, both FDA-recognised consensus standards. Testing was performed by accredited laboratories and demonstrated full compliance with applicable requirements. These updates reflect changes in test methodology, not in intended use or technological characteristics.

In accordance with 21 CFR § 807.92 (b)(1), the subject device maintains the same clinical application as the predicate. Per 21 CFR 807.92(b)(2), the design and safety remain equivalent. As concluded by 21 CFR § 807.92(b)(3), the use of updated standard does not affect safety or effectiveness. FDA recognised documentation including "Guidance for Industry and FDA Staff: Information to Support EMC of Medical Devices[2]") were used to support. The conclusions drawn from the EMC and electrical safety testing confirm that the subject device is as safe, as effective and performs as expected.

Usability and Human Factors

Validation testing was conducted in accordance with IEC 62366-1:2015/A1:2020, employing summative evaluation techniques to assess usability and user interaction. The evaluation was further supported by compliance with FDA recognized guidance documents "*Applying Human Factors and Usability Engineering to Medical Devices*[3]" and "*Content of Human Factors Information in Medical Device Marketing Submissions*[4]". All verification and validation activities demonstrated successful outcomes across all test cases, confirming that the subject device supports safe and effective use. These results support a determination of substantial equivalence in accordance with 21 CFR § 807.92(a)(6) and 21 CFR § 807.92(b)(1-3).

These results confirm that the subject device meets its design specifications and does not raise new questions of safety or effectiveness, supporting a determination of substantial equivalence to the legally marketed predicate device.

Conclusion

AlignRT Plus is substantially equivalent to the predicate device. There have been no changes to the indications for use or the intended use of the device.

Comprehensive verification and validation activities were conducted using established

[1] Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, FDA, accessed September 2025

[2] Guidance for Industry and FDA Staff: Information to Support EMC of Medical Devices, FDA, accessed September 2025

[3] Applying Human Factors and Usability Engineering to Medical Devices, FDA, accessed September 2025

[4] Content of Human Factors Information in Medical Device Marketing Submissions, FDA, accessed September 2025

methods consistent with those applied to the cleared predicate device. The nonclinical evaluations including software testing, electrical safety, EMC, usability and system performance confirm that AlignRT Plus meets all design specifications and performs as intended.

No new technological characteristics have been introduced that would raise new questions of safety or effectiveness. Accordingly, AlignRT Plus is as safe, effective and performs as well as the legally marketed predicate device, supporting a determination of substantial equivalence under 21 CFR § 807.92.