

**K193431 AlignRT Plus**Jan 3, 2020  
24 days to decisionK193431 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k193431/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 10, 2019
Decision date	Jan 3, 2020
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Vision Rt, Ltd.</b>
Location	London, GB
Contact	Arun Mahendran
Website	<a href="http://www.visionrt.com/">http://www.visionrt.com/</a>
510(k) history	8 submissions · 8 cleared · 2018-2026

Vision RT, Ltd. is a Radiology device manufacturer headquartered in London, UK. The company develops Surface Guided Radiation Therapy (SGRT) solutions that use 3D surface imaging to track patients and improve safety, effectiveness, and efficiency throughout the radiotherapy workflow. Over 3,000 systems are in active clinical use globally. Vision RT has received FDA 510(k) clearances from total submissions since 2018, with no denied submissions. All submissions have focused on Radiology devices. The company's latest clearance was in 2026, confirming active regulatory engag...