

K212583 AlignRT PlusNov 10, 2021
86 days to decisionK212583 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k212583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Aug 16, 2021
Decision date	Nov 10, 2021
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vision Rt, Ltd.
Location	London, GB
Contact	Jade Dunphy
Website	http://www.visionrt.com/
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...
