

# K231185 MapRT

Jun 23, 2023  
58 days to decision

K231185 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k231185/>

## SUBMISSION DETAILS

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Apr 26, 2023
Decision date	Jun 23, 2023
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

---

Company	<b>Vision Rt, Ltd.</b>
Location	London, GB
Contact	Jade Dunphy
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...