

**K212958 MRIdian Linac System**Dec 14, 2021  
89 days to decisionK212958 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k212958/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Sep 16, 2021
Decision date	Dec 14, 2021
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Viewray, Incorporated</b>
Location	Oakwood Village, OH, US
Contact	Sean Delaney
510(k) history	6 submissions · 6 cleared · 2011-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212958/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026