

K181989 MRIdian Linac SystemFeb 20, 2019
209 days to decisionK181989 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k181989/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 26, 2018
Decision date	Feb 20, 2019
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181989/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026