

**K100115 XVI R4.5**Mar 10, 2010  
54 days to decisionK100115 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k100115/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jan 15, 2010
Decision date	Mar 10, 2010
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elekta , Ltd.</b>
Location	Norcross, GA, US
Contact	ANDREW HEDGES
Website	<a href="http://www.elekta.com">http://www.elekta.com</a>
510(k) history	10 submissions · 10 cleared · 2005-2014

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100115/>; 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 16, 2026