

**K160440 Leksell Gamma Knife Icon**Apr 20, 2016  
63 days to decisionK160440 · Product code: **IWB** · Radiology  
Source: <https://www.510kdatabase.net/k160440/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	Feb 17, 2016
Decision date	Apr 20, 2016
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elekta Instrument AB</b>
Location	Lake Forest, CA, US
Contact	Alf Laurell
510(k) history	35 submissions · 35 cleared · 1996-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160440/> 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 June 18, 2026