

**K151561 Leksell Gamma Knife Icon**Aug 4, 2015  
55 days to decisionK151561 · Product code: **IWB** · Radiology  
Source: <https://www.510kdatabase.net/k151561/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	Jun 10, 2015
Decision date	Aug 4, 2015
Days to decision	55 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	<b>MATILDA FORSBERG</b>
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/k151561/> 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