

**K151666 Leksell GammaPlan**Sep 3, 2015  
76 days to decisionK151666 · Product code: **MUJ** · Radiology  
Source: <https://www.510kdatabase.net/k151666/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Jun 19, 2015
Decision date	Sep 3, 2015
Days to decision	76 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	MATILDA FORSBERG
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/k151666/> 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