

**K222047 Leksell Gamma Knife Perfexion, Leksell Gamma Knife Icon, Leksell Gamma Knife - Elekta Esprit (New model variant)**Oct 26, 2022  
106 days to decisionK222047 · Product code: **IWB** · Radiology  
Source: <https://www.510kdatabase.net/k222047/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	Jul 12, 2022
Decision date	Oct 26, 2022
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elekta Solutions AB</b>
Location	Stockholm, SE
Contact	Helena Skar
510(k) history	14 submissions · 14 cleared · 2020-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222047/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026