

K250391 Leksell Gamma Knife® (Elekta Esprit)Jul 2, 2025
140 days to decisionK250391 · Product code: **IWB** · Radiology
Source: <https://www.510kdatabase.net/k250391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	Feb 12, 2025
Decision date	Jul 2, 2025
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Leksell Gamma Knife® (Icon™); Leksell Gamma Knife® (Perfexion™)

APPLICANT

Company	Elekta Solutions AB
Location	Stockholm, SE
Contact	Simon Sjöbage
510(k) history	14 submissions · 14 cleared · 2020-2026

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