

K232854 Leksell GammaPlan (LGP)Feb 8, 2024
146 days to decisionK232854 · Product code: **IWB** · Radiology
Source: <https://www.510kdatabase.net/k232854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Radiation Therapy, Radionuclide (IWB)
Date received	Sep 15, 2023
Decision date	Feb 8, 2024
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232854/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026