

K251363 ProKnow DSOct 8, 2025
160 days to decisionK251363 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k251363/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 1, 2025
Decision date	Oct 8, 2025
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251363/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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