FDA 510(k) Premarket Notification

K251363 ProKnow DS

CLEARED

Oct 8, 2025
160 days to decision

K251363 · 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