

K212114 Elekta UnityOct 1, 2021
86 days to decisionK212114 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k212114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 7, 2021
Decision date	Oct 1, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Elekta, Inc.
Contact	Melinda Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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Device record: <https://www.510kdatabase.net/k212114/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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