FDA 510(k) Premarket Notification

K212114 Elekta Unity

CLEARED

Oct 1, 2021
86 days to decision

K212114 · 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