

**K223209 Elekta Unity**Feb 23, 2023  
129 days to decisionK223209 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k223209/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Oct 17, 2022
Decision date	Feb 23, 2023
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223209/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026