

**K182076 Elekta Unity**Dec 4, 2018  
125 days to decisionK182076 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k182076/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Aug 1, 2018
Decision date	Dec 4, 2018
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elekta Limited</b>
Location	West Sussex, GB
Contact	Nicholas Power
510(k) history	8 submissions · 8 cleared · 2011-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182076/> 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 27, 2026