

K131965 XVI R5.0Sep 25, 2013
90 days to decisionK131965 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k131965/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accelerator, Linear, Medical (IYE) |
| Date received | Jun 27, 2013 |
| Decision date | Sep 25, 2013 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Elekta Limited |
| Location | West Sussex, GB |
| Contact | ANDREW HEDGES |
| 510(k) history | 8 submissions · 8 cleared · 2011-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131965/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026