

**K033340 LEKSELL SURGIPLAN WITH IMAGEMERGE**Feb 12, 2004  
118 days to decisionK033340 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k033340/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Special                                   |
| Device classification | Neurological Stereotaxic Instrument (HAW) |
| Date received         | Oct 17, 2003                              |
| Decision date         | Feb 12, 2004                              |
| Days to decision      | 118 days                                  |
| Third-party review    | No  |
| Summary / Statement   | Statement                                 |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Elekta Instrument AB</b>             |
| Location       | Lake Forest, CA, US                     |
| Contact        | PETER LOWENDAHL                         |
| 510(k) history | 35 submissions · 35 cleared · 1996-2019 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033340/> 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 June 18, 2026