

**K031999 ELEKTA LEKSELL STEREOTACTIC SYSTEM WITH MR  
POST KIT**Jul 25, 2003  
28 days to decisionK031999 · Product code: **HAW** · Radiology  
Source: <https://www.510kdatabase.net/k031999/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Special                                   |
| Device classification | Neurological Stereotaxic Instrument (HAW) |
| Date received         | Jun 27, 2003                              |
| Decision date         | Jul 25, 2003                              |
| Days to decision      | 28 days                                   |
| Third-party review    | No  |
| Summary / Statement   | Statement                                 |

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031999/> 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 June 18, 2026