

**K031732 EBI ACUMEN SURGICAL NAVIGATION SYSTEM**Oct 15, 2003  
133 days to decisionK031732 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k031732/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Neurological Stereotaxic Instrument (HAW) |
| Date received         | Jun 4, 2003                               |
| Decision date         | Oct 15, 2003                              |
| Days to decision      | 133 days                                  |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Ebi, L.P.</b>                        |
| Location       | Parsippany, NJ, US                      |
| Contact        | JON CAPAROTTA                           |
| 510(k) history | 95 submissions · 94 cleared · 1997-2010 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031732/> 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 19, 2026