

**K964533 EBI SPINELINK SYSTEM**Apr 9, 1997  
148 days to decisionK964533 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k964533/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Orthosis, Spondylolisthesis Spinal Fixation (MNH) |
| Date received         | Nov 12, 1996                                      |
| Decision date         | Apr 9, 1997                                       |
| Days to decision      | 148 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Electro-Biology, Inc.</b>            |
| Location       | Mchenry, IL, US                         |
| Contact        | SHARON A STAROWICZ                      |
| 510(k) history | 28 submissions · 22 cleared · 1983-1999 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964533/> 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 21, 2026