

**K001627 TRIFIX SPINAL FIXATION SYSTEM**Jun 3, 2000  
8 days to decisionK001627 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k001627/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Special   |
| Device classification | Orthosis, Spondylolisthesis Spinal Fixation (MNH) |
| Date received         | May 26, 2000                                      |
| Decision date         | Jun 3, 2000                                       |
| Days to decision      | 8 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Endius, Inc.</b>                     |
| Location       | Plainville, MA, US                      |
| Contact        | SUSAN FINNERAN                          |
| 510(k) history | 33 submissions · 33 cleared · 1997-2008 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001627/> 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