

**K964805 BIO-ANCHOR**Jun 9, 1997  
192 days to decisionK964805 · Product code: **MAI** · Orthopedic  
Source: <https://www.510kdatabase.net/k964805/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | Fastener, Fixation, Biodegradable, Soft Tissue (MAI) |
| Date received         | Nov 29, 1996   |
| Decision date         | Jun 9, 1997  |
| Days to decision      | 192 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Linvatec Corp.</b>                   |
| Location       | Research Triangle Pa, NC, US            |
| Contact        | CAROL A WEIDEMAN                        |
| 510(k) history | 93 submissions · 87 cleared · 1992-2009 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964805/> 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 14, 2026