

**K033046 SUBTALAR PEG IMPLANT**Dec 23, 2003  
85 days to decisionK033046 · Product code: **MJW** · Orthopedic  
Source: <https://www.510kdatabase.net/k033046/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Prosthesis, Subtalar, Plug, Polymer (MJW) |
| Date received         | Sep 29, 2003                              |
| Decision date         | Dec 23, 2003                              |
| Days to decision      | 85 days                                   |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Nexa Orthopedics, Inc.</b>           |
| Location       | Vista, CA, US                           |
| Contact        | LOUISE M FOCHT                          |
| 510(k) history | 16 submissions · 16 cleared · 1997-2007 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033046/> 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