

**K962646 PRIME MODULAR ENDO HEAD**Sep 23, 1996  
77 days to decisionK962646 · Product code: **KWL** · Orthopedic  
Source: <https://www.510kdatabase.net/k962646/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | Prosthesis, Hip, Hemi-, Femoral, Metal (KWL) |
| Date received         | Jul 8, 1996                                  |
| Decision date         | Sep 23, 1996                                 |
| Days to decision      | 77 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Orthopaedic Innovations, Inc.</b>  |
| Location       | Minneapolis, MN, US                   |
| Contact        | CAROLYN M STEELE-HUSTEN               |
| 510(k) history | 8 submissions · 7 cleared · 1995-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962646/> 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 20, 2026