

**K855228 FEMORAL HEMI-HIP PROSTHESES**Feb 11, 1986  
43 days to decisionK855228 · Product code: **KWL** · Orthopedic  
Source: <https://www.510kdatabase.net/k855228/>**SUBMISSION DETAILS**

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|                       |                                              |
|-----------------------|----------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | Prosthesis, Hip, Hemi-, Femoral, Metal (KWL) |
| Date received         | Dec 30, 1985                                 |
| Decision date         | Feb 11, 1986                                 |
| Days to decision      | 43 days                                      |
| Third-party review    | No                                           |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Orthopaedic Device Corp.</b>       |
| Location       | Paramus, NJ, US                       |
| Contact        | ALEX KHOWAYLO                         |
| 510(k) history | 4 submissions · 4 cleared · 1986-1987 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k855228/>; 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 22, 2026