

**K934353 ZIRCONIUM ALLOY UNI-POLAR HEAD**Apr 25, 1994  
229 days to decisionK934353 · Product code: **KWL** · Orthopedic  
Source: <https://www.510kdatabase.net/k934353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Sep 8, 1993
Decision date	Apr 25, 1994
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smith &amp; Nephew Richards, Inc.</b>
Location	Memphus, TN, US
Contact	THOMAS L CRAIG
510(k) history	87 submissions · 72 cleared · 1990-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934353/> 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 21, 2026