

**K994041 TORNIER BIPOLAR RADIAL HEAD PROSTHESIS**Aug 31, 2000  
276 days to decisionK994041 · Product code: **KWI** · Orthopedic  
Source: <https://www.510kdatabase.net/k994041/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Nov 29, 1999
Decision date	Aug 31, 2000
Days to decision	276 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tornier, Inc.</b>
Location	Beverly, MA, US
Contact	DAVID W SCHLERF
510(k) history	51 submissions · 51 cleared · 2000-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k994041/> 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