

**K994392 AEQUALIS SHOULDER FRACTURE SYSTEM**Mar 10, 2000  
73 days to decisionK994392 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k994392/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Dec 28, 1999
Decision date	Mar 10, 2000
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Tornier</b>
Location	Concord, CA, US
Contact	DAVID W SCHLERF
510(k) history	44 submissions · 44 cleared · 1995-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k994392/> 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 14, 2026