

**K063081 AEQUALIS SHOULDER SYSTEM**Nov 9, 2006  
30 days to decisionK063081 · Product code: **HSD** · Orthopedic  
Source: <https://www.510kdatabase.net/k063081/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (HSD)
Date received	Oct 10, 2006
Decision date	Nov 9, 2006
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063081/> 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