

**K082754 AEQUALIS HUMERAL NAIL SYSTEM**Jan 27, 2009  
130 days to decisionK082754 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k082754/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Sep 19, 2008
Decision date	Jan 27, 2009
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tornier</b>
Location	Concord, CA, US
Contact	BRIAN HODOREK
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/k082754/> 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