

**K191318 AEQUALIS FLEX REVIVE Shoulder System**Jun 14, 2019  
30 days to decisionK191318 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k191318/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	May 15, 2019
Decision date	Jun 14, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tornier, Inc.</b>
Location	Beverly, MA, US
Contact	Katie Molland
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/k191318/> 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