

**K160975 Aequalis PerFORM+ Shoulder System**Jun 10, 2016  
64 days to decisionK160975 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k160975/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Apr 7, 2016
Decision date	Jun 10, 2016
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160975/> 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 17, 2026