

**K143552 Simpliciti Shoulder System**Mar 4, 2015  
79 days to decisionK143552 · Product code: **PKC** · Orthopedic  
Source: <https://www.510kdatabase.net/k143552/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-constrained (PKC)
Date received	Dec 15, 2014
Decision date	Mar 4, 2015
Days to decision	79 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/k143552/> 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