

**K193247 LATITUDE EV™ Total Elbow Arthroplasty**Aug 5, 2020  
254 days to decisionK193247 · Product code: **JDB** · Orthopedic  
Source: <https://www.510kdatabase.net/k193247/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Semi-constrained, Cemented (JDB)
Date received	Nov 25, 2019
Decision date	Aug 5, 2020
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193247/> 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