

**K181837 Spinal Elements Ti-Bond coated devices**Nov 2, 2018  
115 days to decisionK181837 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k181837/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 10, 2018
Decision date	Nov 2, 2018
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Spinal Elements, Inc.</b>
Location	Carlsbad, CA, US
Contact	Julie Lamothe
Website	<a href="https://www.spinalelements.com">https://www.spinalelements.com</a>
510(k) history	48 submissions · 48 cleared · 2007-2026

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181837/> 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 16, 2026