

**K130438 AXLE INTERSPINOUS FUSION SYSTEM**Jun 27, 2013  
126 days to decisionK130438 · Product code: **PEK** · Orthopedic  
Source: <https://www.510kdatabase.net/k130438/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Feb 21, 2013
Decision date	Jun 27, 2013
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>X-Spine Systems, Inc.</b>
Location	Centerville, OH, US
Contact	DAVID KIRSCHMAN, M.D.
510(k) history	34 submissions · 34 cleared · 2005-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130438/> 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 18, 2026