

**K122771 SPINAL ELEMENTS CERVICAL INTERVERTEBRAL  
BODY FUSION SYSTEM**Jan 10, 2013  
122 days to decisionK122771 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k122771/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 10, 2012
Decision date	Jan 10, 2013
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122771/> 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