

**K161280 Cervical Stand Alone System**Jun 17, 2016  
42 days to decisionK161280 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k161280/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	May 6, 2016
Decision date	Jun 17, 2016
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthofix, Inc.</b>
Location	Mckinney, TX, US
Contact	Natalia Volosen
510(k) history	57 submissions · 57 cleared · 1996-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161280/> 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 15, 2026