

**K152475 FORZA PTC Spacer System**Jan 14, 2016  
136 days to decisionK152475 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k152475/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Aug 31, 2015
Decision date	Jan 14, 2016
Days to decision	136 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/k152475/> 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