

**K112696 TWIN PEAKS LUMBAR CAGE**Apr 18, 2012  
216 days to decisionK112696 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k112696/>**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	Sep 15, 2011
Decision date	Apr 18, 2012
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qualgenix, LLC</b>
Location	Oxford, CT, US
Contact	RICHARD DESLAURIERS
510(k) history	2 submissions · 2 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112696/> 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