

**K113348 COUGAR SYSTEM**Dec 13, 2011  
29 days to decisionK113348 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k113348/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 14, 2011
Decision date	Dec 13, 2011
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Johnson &amp; Johnson</b>
Location	Raynham, MA, US
Contact	KEVIN G STEVENS
Website	<a href="http://www.jnj.com">http://www.jnj.com</a>
510(k) history	9 submissions · 9 cleared · 2011-2012

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113348/> 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