

**K083637 CALIX SPINAL IMPLANT SYSTEM**Apr 20, 2009  
132 days to decisionK083637 · Product code: **ODP** · Orthopedic  
Source: <https://www.510kdatabase.net/k083637/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Dec 9, 2008
Decision date	Apr 20, 2009
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>X-Spine Systems, Inc.</b>
Location	Centerville, OH, US
Contact	DAVID KIRSCHMAN
510(k) history	34 submissions · 34 cleared · 2005-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083637/> 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 16, 2026