

**K111166 A-WEDGE ANTERIOR INTERBODY SYSTEM (A-WEDGE A.I.S.)**Sep 8, 2011  
135 days to decisionK111166 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k111166/>**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	Apr 26, 2011
Decision date	Sep 8, 2011
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spineworks, LLC</b>
Location	Washington, DC, US
Contact	J.D. WEBB
510(k) history	4 submissions · 4 cleared · 2005-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111166/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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