

**K092574 ESL SPINAL SYSTEM**Feb 4, 2010  
167 days to decisionK092574 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k092574/>**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 21, 2009
Decision date	Feb 4, 2010
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ebi, L.P.</b>
Location	Parsippany, NJ, US
Contact	VIVIAN KELLY
510(k) history	95 submissions · 94 cleared · 1997-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092574/> 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