

**K082406 EXPANDABLE PEEK-OPTIMA IMPLANT**Jan 14, 2009  
146 days to decisionK082406 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k082406/>**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, 2008
Decision date	Jan 14, 2009
Days to decision	146 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/k082406/> 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 19, 2026