

**K072791 ORACLE SPACER, OPAL SPACER**Dec 26, 2007  
86 days to decisionK072791 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k072791/>**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	Oct 1, 2007
Decision date	Dec 26, 2007
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synthes Spine</b>
Location	Paoli, PA, US
Contact	STACEY BONNELL
510(k) history	36 submissions · 32 cleared · 1995-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072791/> 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