

**K091159 SYNTHES ORACLE PLATE**Jul 10, 2009  
80 days to decisionK091159 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k091159/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Apr 21, 2009
Decision date	Jul 10, 2009
Days to decision	80 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/k091159/> 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