

**K091359 GSO PCT SPINAL SYSTEM**Sep 2, 2009  
117 days to decisionK091359 · Product code: **KWP** · Orthopedic  
Source: <https://www.510kdatabase.net/k091359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	May 8, 2009
Decision date	Sep 2, 2009
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gold Standard Orthopaedics, LLC</b>
Location	Louisville, KY, US
Contact	DAVID BAUGHMAN
510(k) history	4 submissions · 4 cleared · 2007-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091359/> 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