

**K013442 PASS SPINAL SYSTEM**Jan 15, 2002  
90 days to decisionK013442 · Product code: **KWP** · Orthopedic  
Source: <https://www.510kdatabase.net/k013442/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Oct 17, 2001
Decision date	Jan 15, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Encore Orthopedics, Inc.</b>
Location	Red Rock, TX, US
Contact	JOANNA DROEGE
510(k) history	85 submissions · 74 cleared · 1993-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013442/> 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 20, 2026