

**K042508 SUMIT OCT SPINAL SYSTEM AND MOUNTAINEER  
OCT SPINAL SYSTEM**Oct 7, 2004  
22 days to decisionK042508 · Product code: **KWP** · Orthopedic  
Source: <https://www.510kdatabase.net/k042508/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Interlaminar (KWP)
Date received	Sep 15, 2004
Decision date	Oct 7, 2004
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Depuy Spine, Inc.</b>
Location	Raynham, MA, US
Contact	SHARON STAROWICZ
510(k) history	68 submissions · 67 cleared · 2004-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042508/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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