

**K080828 MOUNTAINEER OCT SPINAL SYSTEM**Jun 27, 2008  
94 days to decisionK080828 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k080828/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Mar 25, 2008
Decision date	Jun 27, 2008
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Depuy Spine, Inc.</b>
Location	Raynham, MA, US
Contact	LISA GILMAN
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/k080828/> 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 June 19, 2026