

**K100377 DIAMONDBACK SPINAL SYSTEM**Apr 22, 2010  
69 days to decisionK100377 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k100377/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Feb 12, 2010
Decision date	Apr 22, 2010
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eminent Spine</b>
Location	Leander, TX, US
Contact	KAREN WARDEN
510(k) history	11 submissions · 11 cleared · 2009-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100377/> 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 26, 2026