

**K081228 CAPSURE PS (R) SPINE SYSTEM**May 12, 2008  
12 days to decisionK081228 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k081228/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Apr 30, 2008
Decision date	May 12, 2008
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spine Wave, Inc.</b>
Location	Shelton, CT, US
Contact	ROAIDA RIZKALLAH
510(k) history	57 submissions · 57 cleared · 2004-2025

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