

**K071668 ORTHOBIOM SPINAL SYSTEM**Jul 2, 2008  
379 days to decisionK071668 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k071668/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jun 19, 2007
Decision date	Jul 2, 2008
Days to decision	379 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Paradigm Spine</b>
Location	New York, NY, US
Contact	MARCI HALEVI
510(k) history	3 submissions · 3 cleared · 2008-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071668/> 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 27, 2026