

**K032394 STRYKER SPINE OASYS SYSTEM**Feb 20, 2004  
200 days to decisionK032394 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k032394/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Aug 4, 2003
Decision date	Feb 20, 2004
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Howmedica Osteonics Corp.</b>
Location	Allendale, NJ, US
Contact	KAREN ARIEMMA
510(k) history	288 submissions · 288 cleared · 1999-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032394/> 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 15, 2026