

**K053623 NFIX FUSION SYSTEM**Jul 12, 2006  
196 days to decisionK053623 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k053623/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Dec 28, 2005
Decision date	Jul 12, 2006
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>N-Spine, Inc.</b>
Location	Stillwater, MN, US
Contact	ELAINE DUNCAN
510(k) history	3 submissions · 1 cleared · 2006-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053623/> 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 19, 2026