

**K042453 MODIFICATION TO EQUATION FIXATION SYSTEM**Oct 7, 2004  
27 days to decisionK042453 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k042453/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Sep 10, 2004
Decision date	Oct 7, 2004
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek, Inc.</b>
Location	Memphis, TN, US
Contact	RICHARD TREHARNE
510(k) history	99 submissions · 89 cleared · 2000-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042453/> 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 17, 2026