

**K031585 U&I, OPTIMA, SPINAL SYSTEM**Jun 27, 2003  
37 days to decisionK031585 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k031585/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	May 21, 2003
Decision date	Jun 27, 2003
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>U&amp;I Corp., America</b>
Location	Murray, UT, US
Contact	PATRICK MOORE
510(k) history	3 submissions · 3 cleared · 2003-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031585/> 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 20, 2026