

**K043578 THE 4CIS SPINAL SYSTEM AND 4CIS LOW BACK SYSTEM**Mar 7, 2005  
69 days to decisionK043578 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k043578/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Dec 28, 2004
Decision date	Mar 7, 2005
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Solco Biomedical Co., Ltd.</b>
Location	Bethesda, MD, US
Contact	SAEYOUNG AHN
510(k) history	17 submissions · 17 cleared · 2005-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043578/>; 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 26, 2026