

**K012971 ISOLA SPINAL SYSTEMS**Oct 5, 2001  
30 days to decisionK012971 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k012971/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Sep 5, 2001
Decision date	Oct 5, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Depuyacromed</b>
Location	Raynham, MA, US
Contact	LISA GILMAN
510(k) history	48 submissions · 48 cleared · 1999-2004

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