

**K021148 MONARCH SPINE SYSTEM COMMERCIALY PURE  
TITANIUM SPINAL ROD**

May 8, 2002  
28 days to decision

K021148 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k021148/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Apr 10, 2002
Decision date	May 8, 2002
Days to decision	28 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k021148/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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