

**K013222 SUMMIT OCCIPITO-CERVICO- THORACIC (OCT)  
SPINAL SYSTEM**

Nov 7, 2001  
41 days to decision

K013222 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k013222/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Sep 27, 2001
Decision date	Nov 7, 2001
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Depuyacromed</b>
Location	Raynham, MA, US
Contact	KAREN F JURCZAK
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/k013222/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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