

K010576 MONARCH SPINE SYSTEMMay 23, 2001
85 days to decisionK010576 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k010576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Feb 27, 2001
Decision date	May 23, 2001
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Depuyacromed
Location	Raynham, MA, US
Contact	FRANK MAAS
510(k) history	48 submissions · 48 cleared · 1999-2004

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