

K131343 REFORM PEDICLE SCREW SYSTEMJul 24, 2013
76 days to decisionK131343 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k131343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	May 9, 2013
Decision date	Jul 24, 2013
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spinal USA
Location	Brandon, MS, US
Contact	MEREDITH MAY
510(k) history	23 submissions · 23 cleared · 2006-2013

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