

K152132 X-spine Pedicle Screw SystemSep 25, 2015
56 days to decisionK152132 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k152132/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jul 31, 2015
Decision date	Sep 25, 2015
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	X-Spine Systems, Inc.
Location	Centerville, OH, US
Contact	David Kirschman
510(k) history	34 submissions · 34 cleared · 2005-2018

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