

K160320 PremierApr 1, 2016
56 days to decisionK160320 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k160320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Feb 5, 2016
Decision date	Apr 1, 2016
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Weigao Orthopaedic Device Co., Ltd.
Location	Weihai, CN
Contact	Han Wang
510(k) history	2 submissions · 2 cleared · 2016-2017

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