

**K150647 Polyscrew Pedicle Screw System**Apr 8, 2015  
27 days to decisionK150647 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k150647/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Mar 12, 2015
Decision date	Apr 8, 2015
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>New Era Orthopedics, LLC</b>
Location	Hummelstown, PA, US
Contact	Mark De Baca
510(k) history	2 submissions · 2 cleared · 2014-2015

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