

**K141253 NEW ERA ORTHOPAEDICS POLYSCREW PEDICLE
SCREW SYSTEM**Jan 9, 2015
240 days to decisionK141253 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k141253/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	May 14, 2014
Decision date	Jan 9, 2015
Days to decision	240 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	New Era Orthopaedics, LLC
Location	Round Rock, TX, US
Contact	J.D. WEBB
510(k) history	1 submissions · 1 cleared · 2015-2015

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