

**K143222 FIREFLY Pedicle Screw Navigation Guide**Dec 11, 2015  
396 days to decisionK143222 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k143222/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Nov 10, 2014
Decision date	Dec 11, 2015
Days to decision	396 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mighty Oak Medical, Inc.</b>
Location	Englewood, CO, US
Contact	Heidi Frey
510(k) history	5 submissions · 5 cleared · 2015-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143222/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026