

**K150380 ProMIS Fixation System**Jul 17, 2015  
154 days to decisionK150380 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k150380/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 13, 2015
Decision date	Jul 17, 2015
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Premia Spine, Ltd.</b>
Location	Ramat Poleg, IL
Contact	Ron Sacher
510(k) history	6 submissions · 6 cleared · 2015-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150380/> 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