

**K232719 ProMIS Extension Rod System**Nov 21, 2023  
77 days to decisionK232719 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k232719/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 5, 2023
Decision date	Nov 21, 2023
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Premia Spine, Ltd.</b>
Location	Ramat Poleg, IL
Contact	Dorit Winitz
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/k232719/> 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