

**K161627 PASS LP Spinal System**Jul 29, 2016  
46 days to decisionK161627 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k161627/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 13, 2016
Decision date	Jul 29, 2016
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea International SA</b>
Location	Neyron, FR
Contact	DAVID RYAN
510(k) history	25 submissions · 25 cleared · 2015-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161627/> 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 17, 2026