

**K162786 PASS LP Spinal System**Jan 25, 2017  
114 days to decisionK162786 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k162786/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 3, 2016
Decision date	Jan 25, 2017
Days to decision	114 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/k162786/> 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 16, 2026