

**K172175 CapSure® PS System**Aug 16, 2017  
28 days to decisionK172175 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k172175/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 19, 2017
Decision date	Aug 16, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spine Wave, Inc.</b>
Location	Shelton, CT, US
Contact	Amy Nocchioli
510(k) history	57 submissions · 57 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172175/> 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