

**K170528 Sterispine™ PS**Mar 9, 2017  
15 days to decisionK170528 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k170528/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 22, 2017
Decision date	Mar 9, 2017
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Safe Orthopaedics</b>
Location	Eragny Sur Oise, FR
Contact	Pierre Dumouchel
510(k) history	13 submissions · 13 cleared · 2011-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170528/> 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 June 18, 2026