

**K180301 AXIS 5.5 Lumbar Pedicle Screw System**Apr 10, 2018  
67 days to decisionK180301 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k180301/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 2, 2018
Decision date	Apr 10, 2018
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Axis Orthopaedics</b>
Location	Soldotna, AK, US
Contact	Craig Wilcox
510(k) history	3 submissions · 3 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Coorstek Medical</b>
Contact	Steve Brown

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180301/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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