

**K180458 FOCUS Pedicle Screw System**Apr 17, 2018  
56 days to decisionK180458 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k180458/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 20, 2018
Decision date	Apr 17, 2018
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nvision Biomedical Technologies, LLC</b>
Location	San Antonio, TN, US
Contact	Diana Langham
510(k) history	10 submissions · 10 cleared · 2014-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Acknowledge Regulatory Strategies, LLC</b>
Contact	Allison C. Komiyama

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

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