

**K182283 FUSE Pedicle Screw System**Oct 23, 2018  
61 days to decisionK182283 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k182283/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 23, 2018
Decision date	Oct 23, 2018
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Black Box Medical</b>
Location	Midland, TX, US
Contact	Todd Stanaford
510(k) history	2 submissions · 2 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Surgop Support</b>
Contact	Daniel Lanois

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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