

**K182478 Whistler Modular Pedicle Screw System**Jan 15, 2019  
127 days to decisionK182478 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k182478/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 10, 2018
Decision date	Jan 15, 2019
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Evolution Spine, LLC</b>
Location	Dallas, TX, US
Contact	Douglas Davis
510(k) history	5 submissions · 5 cleared · 2016-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182478/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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