

**K181995 Chiral Surgical Pedicle Screw System**Sep 20, 2018  
56 days to decisionK181995 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k181995/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 26, 2018
Decision date	Sep 20, 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>Chiral Surgical</b>
Location	Irvine, CA, US
Contact	Andy Choi
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Empirical Consulting, LLC</b>
Contact	Meredith Lee May

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/k181995/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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