

**K172826 Cellent Spinal Systems**Oct 10, 2018  
387 days to decisionK172826 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k172826/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 18, 2017
Decision date	Oct 10, 2018
Days to decision	387 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Trauhui Medical Instrument Co., Ltd.</b>
Location	Changzhou, CN
Contact	Zhou Yu
510(k) history	2 submissions · 2 cleared · 2018-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Guangzhou Osmunda Medical Device Technical Service Co., Ltd.</b>
Contact	Mike Gu

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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