

**K190408 Spinal Fixation System**Jun 16, 2020  
481 days to decisionK190408 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k190408/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 21, 2019
Decision date	Jun 16, 2020
Days to decision	481 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shangdong Kangsheng Medical Devices Co., Ltd.</b>
Location	Tai'ang City, CN
Contact	Wenxing Dong
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medwheat (Shanghai) Medical Technology Co. , Ltd.</b>
Contact	Jonathan Hu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190408/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 28, 2026