

**K252542 LEO Spinal System**Apr 29, 2026  
260 days to decisionK252542 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k252542/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 12, 2025
Decision date	Apr 29, 2026
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>ZheJiang Decans Medical Devices Co., Ltd.</b>
Location	Jiaxing, CN
Contact	Haifeng Liu
510(k) history	6 submissions · 6 cleared · 2024-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sinow Medical AS</b>
Contact	Xiaoqing Xue

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/k252542/> 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 May 13, 2026