

**K252730 Fule Spinal Fixation System**Oct 24, 2025  
57 days to decisionK252730 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k252730/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 28, 2025
Decision date	Oct 24, 2025
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beijing Fule Science &amp; Technology Development Co., Ltd.</b>
Location	Beijing, CN
Contact	Xiaoliang Chen
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252730/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026