

**K172267 IRENE Thoracolumbar Fixation System**Mar 6, 2018  
222 days to decisionK172267 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k172267/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 27, 2017
Decision date	Mar 6, 2018
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tianjin Zhengtian Medical Instrument Co., Ltd.</b>
Location	Tianjin, CN
Contact	Ou Changli
510(k) history	3 submissions · 3 cleared · 2016-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172267/> 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 16, 2026