

**K143013 Spinal Inner Fixation System**Dec 11, 2015  
417 days to decisionK143013 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k143013/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Oct 20, 2014
Decision date	Dec 11, 2015
Days to decision	417 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Changzhou Dingjian Medical Appliance Co., Ltd.</b>
Location	Changzhou, CN
Contact	Li Quinsong
510(k) history	2 submissions · 2 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143013/> 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 17, 2026