

**K151458 Double Medical Universal Spine System**Aug 22, 2016  
448 days to decisionK151458 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k151458/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jun 1, 2015
Decision date	Aug 22, 2016
Days to decision	448 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Double Medical Technology, Inc.</b>
Location	Xiamen, CN
Contact	DA ZENG
510(k) history	12 submissions · 12 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151458/> 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 26, 2026