

**K100765 FIXPINE II SYSTEM**Jul 19, 2010  
124 days to decisionK100765 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k100765/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Mar 17, 2010
Decision date	Jul 19, 2010
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dio Medical Co., Ltd.</b>
Location	Santa Fe Springs, CA, US
Contact	JOYCE BANG
510(k) history	7 submissions · 7 cleared · 2010-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100765/> 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