

**K152098 ODALYS Pedicle Screw System**Sep 17, 2015  
51 days to decisionK152098 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k152098/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jul 28, 2015
Decision date	Sep 17, 2015
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kisco International</b>
Location	Saint-Priest, FR
Contact	Hiroko Ito
510(k) history	1 submissions · 1 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152098/> 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