

**K103102 LEUCADIA PEDICLE SCREW SYSTEM**Feb 8, 2011  
111 days to decisionK103102 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k103102/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Oct 20, 2010
Decision date	Feb 8, 2011
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Phygen, LLC</b>
Location	Irvine, CA, US
Contact	HARTMUT LOCH
510(k) history	7 submissions · 7 cleared · 2011-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103102/> 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 18, 2026