

**K111370 ODALYS PEDICLE SCREW SYSTEM**Sep 21, 2011  
128 days to decisionK111370 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k111370/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	May 16, 2011
Decision date	Sep 21, 2011
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kalitec Direct, LLC</b>
Location	Round Rock, TX, US
Contact	J.D. WEBB
510(k) history	9 submissions · 9 cleared · 2011-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111370/> 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