

**K140678 COSMOLOCK PEDICLE SCREW SYSTEM**Jun 19, 2014  
93 days to decisionK140678 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k140678/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Mar 18, 2014
Decision date	Jun 19, 2014
Days to decision	93 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/k140678/> 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