

**K123138 PASS LP SPINAL SYSTEM**Feb 5, 2013  
123 days to decisionK123138 · Product code: **OSH** · Orthopedic  
Source: <https://www.510kdatabase.net/k123138/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis (OSH)
Date received	Oct 5, 2012
Decision date	Feb 5, 2013
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicrea International</b>
Location	Round Rock, TX, US
Contact	LAURE AVIRON-VIOLET
510(k) history	17 submissions · 16 cleared · 2011-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123138/> 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 27, 2026