

**K141508 ROMEO 2 PAD POSTERIOR AXIAL DEVICE**Aug 21, 2014  
76 days to decisionK141508 · Product code: **PEK** · Orthopedic  
Source: <https://www.510kdatabase.net/k141508/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Jun 6, 2014
Decision date	Aug 21, 2014
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spineart</b>
Location	Geneva, CH
Contact	FRANCK PENNESI
510(k) history	44 submissions · 44 cleared · 2008-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141508/> 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