

**K132968 UNIVISE SPINOUS PROCESS FIXATION PLATE  
(35MM, 40MM)**Nov 18, 2013  
56 days to decisionK132968 · Product code: **PEK** · Orthopedic  
Source: <https://www.510kdatabase.net/k132968/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Sep 23, 2013
Decision date	Nov 18, 2013
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Stryker Spine</b>
Location	Allendale, NJ, US
Contact	KRISTEN MEANY, MS, CQA, RAC
510(k) history	74 submissions · 73 cleared · 2004-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132968/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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