

**K231807 primaLOK™ SP Interspinous Fusion System**Aug 15, 2023  
56 days to decisionK231807 · Product code: **PEK** · Orthopedic  
Source: <https://www.510kdatabase.net/k231807/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Jun 20, 2023
Decision date	Aug 15, 2023
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wenzel Spine, Inc.</b>
Location	Austin, TX, US
Contact	William Wilson
510(k) history	6 submissions · 6 cleared · 2013-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231807/> 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 26, 2026