

K251791 Auxano® Wedge Fixation SystemSep 25, 2025
106 days to decisionK251791 · Product code: **PLF** · Orthopedic
Source: <https://www.510kdatabase.net/k251791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Wedge (PLF)
Date received	Jun 11, 2025
Decision date	Sep 25, 2025
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Auxano Medical, LLC
Location	Brecksville, OH, US
Contact	Stephen Mezget
510(k) history	2 submissions · 2 cleared · 2023-2025

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