

K252254 Osteotomy Wedge SystemOct 17, 2025
88 days to decisionK252254 · Product code: **PLF** · Orthopedic
Source: <https://www.510kdatabase.net/k252254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Wedge (PLF)
Date received	Jul 21, 2025
Decision date	Oct 17, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sinaptic Surgical
Location	Slat Lake City, UT, US
Contact	Brian Hockett
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252254/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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