

K231649 Intraosseous Fusion Device SystemSep 29, 2023
115 days to decisionK231649 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k231649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 6, 2023
Decision date	Sep 29, 2023
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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