

K252758 Cannulated Screw and Kirschner (K wire) SystemOct 2, 2025
34 days to decisionK252758 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k252758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 29, 2025
Decision date	Oct 2, 2025
Days to decision	34 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthonovis, Inc.
Location	Palm Coast, FL, US
Contact	Ken West
510(k) history	5 submissions · 5 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Simple Path, LLC
Contact	Tawney Schwarz

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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