FDA 510(k) Premarket Notification

K252758 Cannulated Screw and Kirschner (K wire) System

CLEARED

Oct 2, 2025
34 days to decision

K252758 · 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