

K250251 Eleganz Fusion Screw System (Fusion Screw System)Jun 13, 2025
136 days to decisionK250251 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k250251/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jan 28, 2025
Decision date	Jun 13, 2025
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dev4
Location	Houston, TX, US
Contact	Jeff Seavey
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Omedtech, LLC
Contact	Lance Terrill

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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