

K261145 Avanti Distal Elbow ORIF SystemMay 9, 2026
32 days to decisionK261145 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k261145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 7, 2026
Decision date	May 9, 2026
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avanti Orthopaedics, LLC
Location	Wilmington, DE, US
Contact	Doug Patterson
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Secure BioMed Evaluations
Contact	Justin Gracyalny

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

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