

K252699 CoAptix S SystemApr 10, 2026
226 days to decisionK252699 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k252699/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 27, 2025
Decision date	Apr 10, 2026
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	University of Utah, Department of Orthopaedics
Location	Salt Lake City, UT, US
Contact	Wade Fallin
510(k) history	2 submissions · 2 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Dave McGurl

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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