

K250867 Dunamis Screw and Suture Locking SystemAug 15, 2025
144 days to decisionK250867 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k250867/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Mar 24, 2025
Decision date	Aug 15, 2025
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dunamis Medical, LLC
Location	Greenville, AL, US
Contact	PrithviRaj Chavan
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Sarah Pleaugh

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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