

**K230867 Bone Bolt System**Jun 26, 2023  
89 days to decisionK230867 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k230867/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Mar 29, 2023
Decision date	Jun 26, 2023
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Hollace Rhodes

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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