

**K252019 CurvaFix Low Profile System**Aug 29, 2025  
60 days to decisionK252019 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k252019/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 30, 2025
Decision date	Aug 29, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Curvafix, Inc.</b>
Location	Bellevue, WA, US
Contact	Mark Foster
510(k) history	3 submissions · 3 cleared · 2019-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>DuVal &amp; Associates, P.A.</b>
Contact	Lisa L. Pritchard

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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