FDA 510(k) Premarket Notification

K252019 CurvaFix Low Profile System

CLEARED

Aug 29, 2025
60 days to decision

K252019 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k252019/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**DuVal & Associates, P.A.**
Contact	Lisa L. Pritchard

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