

K180377 Fracture and Correction SystemJun 20, 2018
128 days to decisionK180377 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k180377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 12, 2018
Decision date	Jun 20, 2018
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	In2bones USA, LLC
Location	Memphis, TN, US
Contact	Rebecca Wahl
510(k) history	25 submissions · 25 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180377/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 15, 2026