

K200226 RetroFixJun 26, 2020
148 days to decisionK200226 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k200226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jan 30, 2020
Decision date	Jun 26, 2020
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Retrofix Screws, LLC
Location	Salisbury, NC, US
Contact	Keith A Barritt
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Fish & Richardson, P.C.
Contact	Keith A Barritt

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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