

**K181610 ActivOrtho Nitinol Compression Screw System**Mar 12, 2019  
266 days to decisionK181610 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k181610/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 19, 2018
Decision date	Mar 12, 2019
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Activortho, Inc.</b>
Location	Plymouth, MN, US
Contact	Paul Hindrichs
510(k) history	2 submissions · 2 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Backroads Consulting, Inc.</b>
Contact	Karen E. Warden

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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