FDA 510(k) Premarket Notification

K181610 ActivOrtho Nitinol Compression Screw System

CLEARED

Mar 12, 2019
266 days to decision

K181610 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k181610/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Backroads Consulting, Inc.**
Contact	Karen E. Warden

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