FDA 510(k) Premarket Notification

K191289 Bone Screw Line Addition

CLEARED

Jul 29, 2019
77 days to decision

K191289 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k191289/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	May 13, 2019
Decision date	Jul 29, 2019
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vilex IN Tennessee, Inc.**
Location	Lakewood Ranch, FL, US
Contact	Victor Lavi
510(k) history	7 submissions · 7 cleared · 2014-2019