

K191289 Bone Screw Line AdditionJul 29, 2019
77 days to decisionK191289 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191289/> 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 June 28, 2026