FDA 510(k) Premarket Notification

K250304 TITANEX Screw Systems

CLEARED

Mar 5, 2025
30 days to decision

K250304 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k250304/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 3, 2025
Decision date	Mar 5, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vilex, LLC**
Location	Mcminnville, TN, US
Contact	Scott Armacost
Website	https://www.vilex.com
510(k) history	17 submissions · 17 cleared · 2020-2026

Vilex, LLC is a dedicated lower extremity medical device company specializing in foot and ankle surgical solutions. Based in McMinnville, Tennessee, Vilex develops and markets an innovative portfolio of orthopedic implants and surgical systems designed by surgeons for surgeons. The company has received FDA 510(k) clearances from total submissions since 2020. Vilex maintains a 100% clearance rate in the orthopedic device category, with its most recent FDA 510(k) clearance in 2026, demonstrating continued active development and regulatory engagement. Vilex's product portfol...