FDA 510(k) Premarket Notification

CLEARED

K231493 NITINEX Memory Compression Staple

Aug 11, 2023
80 days to decision

K231493 · Product code: **JDR** · Orthopedic
Source: https://www.510kdatabase.net/k231493/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	May 23, 2023
Decision date	Aug 11, 2023
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vilex, LLC**
Location	Mcminnville, TN, US
Contact	Brock Johnson
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...