

**K240035 TACTIX Vector Syndesmosis System**Aug 1, 2024  
210 days to decisionK240035 · Product code: **HTN** · Orthopedic  
Source: <https://www.510kdatabase.net/k240035/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Washer, Bolt Nut (HTN)
Date received	Jan 4, 2024
Decision date	Aug 1, 2024
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vilex, LLC</b>
Location	Mcminnville, TN, US
Contact	Brock Johnson
Website	<a href="https://www.vilex.com">https://www.vilex.com</a>
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...