

K202054 Dynex Ring Fixation System, Diametrix Ring Fixation System

Aug 24, 2020
31 days to decision

K202054 · Product code: KTT · Orthopedic
Source: <https://www.510kdatabase.net/k202054/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Jul 24, 2020
Decision date	Aug 24, 2020
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vilex, LLC
Location	Mcminnville, TN, US
Contact	Joyce Thacker
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...

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Device record: <https://www.510kdatabase.net/k202054/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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