FDA 510(k) Premarket Notification

K221342 REDEMPTION Beaming System

CLEARED

Dec 13, 2022
218 days to decision

K221342 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k221342/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	May 9, 2022
Decision date	Dec 13, 2022
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vilex, LLC**
Location	Mcminnville, TN, US
Contact	Louis Monaco
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...

REGULATORY CONSULTANT

Consulting firm	**Telos Partners, LLC**
Contact	Roshana Ahmed

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov