

K230462 OPTIX H2 Patient Specific Instrument SystemJul 17, 2023
146 days to decisionK230462 · Product code: **HSN** · Orthopedic
Source: <https://www.510kdatabase.net/k230462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Ankle, Semi-constrained, Cemented, Metal/polymer (HSN)
Date received	Feb 21, 2023
Decision date	Jul 17, 2023
Days to decision	146 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...