

K252087 Navigation Module of the Cortium® SystemFeb 3, 2026
216 days to decisionK252087 · Product code: **OLO** · Orthopedic
Source: <https://www.510kdatabase.net/k252087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Jul 2, 2025
Decision date	Feb 3, 2026
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ulrich Medical USA, Inc.
Location	Plano, TX, US
Contact	Eric Lucas
Website	https://www.ulrichmedical.com
510(k) history	4 submissions · 4 cleared · 2024-2026

Ulrich Medical USA, Inc. is a medical technology company specializing in orthopedic surgical devices. The company operates with a manufacturing facility in Plano, Texas. Ulrich Medical is known for its "Made in Germany" engineering approach and comprehensive spinal surgery solutions. The company has received FDA 510(k) clearances from total submissions. All submissions have focused on orthopedic devices, reflecting the company's specialized expertise in spinal fixation and fusion technologies. First clearance in 2024 and latest clearance in 2026 demonstrate active regulat...

REGULATORY CONSULTANT

Consulting firm	Empirical Technologies
Contact	Hannah Taggart

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

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Device record: <https://www.510kdatabase.net/k252087/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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