

**K240515 uNion® MAX Cervical Plate System**Mar 18, 2024  
24 days to decisionK240515 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k240515/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 23, 2024
Decision date	Mar 18, 2024
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ulrich Medical USA, Inc.</b>
Location	Plano, TX, US
Contact	Eric Lucas
Website	<a href="https://www.ulrichmedical.com">https://www.ulrichmedical.com</a>
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...