

K231739 Cervical Spine Truss System (CSTS)Sep 25, 2023
103 days to decisionK231739 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k231739/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jun 14, 2023
Decision date	Sep 25, 2023
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	4Web Medical, Inc.
Location	Frisco, TX, US
Contact	Lewis Harrison
510(k) history	11 submissions · 11 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Silver Pine Consulting
Contact	Richard Jansen

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

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