

**K223362 Cervical Spine Truss System - Stand Alone (CSTS-SA)
Interbody Fusion Device**Feb 2, 2023
91 days to decisionK223362 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k223362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Nov 3, 2022
Decision date	Feb 2, 2023
Days to decision	91 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223362/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026