

K211388 Lateral Spine Truss System (LSTS) Interbody Fusion DeviceAug 5, 2021
92 days to decisionK211388 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k211388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 5, 2021
Decision date	Aug 5, 2021
Days to decision	92 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/k211388/> 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 26, 2026