FDA 510(k) Premarket Notification

CLEARED

K211388 Lateral Spine Truss System (LSTS) Interbody Fusion Device

Aug 5, 2021
92 days to decision

K211388 · 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