FDA 510(k) Premarket Notification

K243934 Stable-L Lumbar Interbody System

CLEARED

Apr 30, 2025
131 days to decision

K243934 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k243934/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Dec 20, 2024
Decision date	Apr 30, 2025
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nexus Spine, LLC**
Location	Salt Lake City, UT, US
Contact	Jared Crocker
Website	https://nexusspine.com
510(k) history	17 submissions · 17 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	**MRC Global**
Contact	Christine Scifert

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