FDA 510(k) Premarket Notification

K231486 Stable-L Standalone Lumbar Interbody System

CLEARED

Oct 12, 2023
142 days to decision

K231486 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k231486/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	May 23, 2023
Decision date	Oct 12, 2023
Days to decision	142 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