FDA 510(k) Premarket Notification

K241467 Stable-C Interbody System

CLEARED

Jul 17, 2024
55 days to decision

K241467 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k241467/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	May 23, 2024
Decision date	Jul 17, 2024
Days to decision	55 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