FDA 510(k) Premarket Notification

K212853 Cervical Stand-Alone System

CLEARED

Nov 5, 2021
59 days to decision

K212853 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k212853/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 7, 2021
Decision date	Nov 5, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eminent Spine, LLC**
Location	Plano, TX, US
Contact	Stephen Courtney
510(k) history	4 submissions · 4 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Meredith Lee May

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