FDA 510(k) Premarket Notification

CLEARED

K212701 Eminent Spine 3D Cervical Interbody Fusion System

Feb 6, 2023
530 days to decision

K212701 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k212701/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Aug 25, 2021
Decision date	Feb 6, 2023
Days to decision	530 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eminent Spine**
Location	Leander, TX, US
Contact	Stephen Courtney
510(k) history	11 submissions · 11 cleared · 2009-2025

REGULATORY CONSULTANT

Consulting firm	**Jalex Medical**
Contact	Jennifer Palinchik

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