FDA 510(k) Premarket Notification

K223231 Ti-Largo Cervical Interbody System

CLEARED

Feb 24, 2023
129 days to decision

K223231 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k223231/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Oct 18, 2022
Decision date	Feb 24, 2023
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Flospine**
Location	Fr. Myers, FL, US
Contact	Peter Harris
510(k) history	4 submissions · 4 cleared · 2014-2023

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert A Poggie

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