FDA 510(k) Premarket Notification

K221578 Hexanium ACIF

CLEARED

Nov 14, 2022
166 days to decision

K221578 · Product code: **OVE** · Orthopedic
Source: https://www.510kdatabase.net/k221578/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jun 1, 2022
Decision date	Nov 14, 2022
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Spinevision, S.A.S.**
Location	Antony, FR
Contact	Quang Tran
510(k) history	5 submissions · 5 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	**Lince Consulting, LLC**
Contact	Nancy Lince

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