FDA 510(k) Premarket Notification

CLEARED

K230478 Acro Composites Interbody System

Oct 19, 2023
239 days to decision

K230478 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k230478/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 22, 2023
Decision date	Oct 19, 2023
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Acro Composites, LLC**
Location	Brecksville, OH, US
Contact	Mitchell Bass
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Backroads Consulting, Inc.**
Contact	Karen E. Warden

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