FDA 510(k) Premarket Notification

CLEARED

K230936 Anatomic PEEK™ Cervical Fusion System with Nanotechnology

Jun 2, 2023
60 days to decision

K230936 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k230936/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Apr 3, 2023
Decision date	Jun 2, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nanovis, LLC**
Location	San Diego, CA, US
Contact	Brian More
510(k) history	10 submissions · 10 cleared · 2011-2024

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k230936/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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