

K241605 Adaptix™ PEEK Interbody System with NanotechnologySep 5, 2024
93 days to decisionK241605 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k241605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 4, 2024
Decision date	Sep 5, 2024
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Capstone Control™ PEEK Spinal System with Nanotechnology

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 Warden

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

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