

K212038 K&J IVA (ACIF, DLIF, PLIF, TLIF, ALIF) PEEK CageAug 27, 2021
58 days to decisionK212038 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k212038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jun 30, 2021
Decision date	Aug 27, 2021
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	K&J Consulting Corporation
Location	Lansdale, PA, US
Contact	Barry E. Sands
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	RQMIS, Inc.
Contact	Barry E. Sands

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026