FDA 510(k) Premarket Notification

K212038 K&J IVA (ACIF, DLIF, PLIF, TLIF, ALIF) PEEK Cage

CLEARED

Aug 27, 2021
58 days to decision

K212038 · 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