FDA 510(k) Premarket Notification

CLEARED

K250335 IVA & AEON Cervical and Lumbar Cage System

Aug 29, 2025
205 days to decision

K250335 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k250335/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 5, 2025
Decision date	Aug 29, 2025
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**K&J Consulting**
Location	Lansdale, PA, US
Contact	Milan George
510(k) history	1 submissions · 1 cleared · 2025-2025