FDA 510(k) Premarket Notification

K250845 Curiteva Porous PEEK Standalone ALIF System

CLEARED

Jun 18, 2025
90 days to decision

K250845 · Product code: **OVD** · Orthopedic
Source: https://www.510kdatabase.net/k250845/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Mar 20, 2025
Decision date	Jun 18, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Curiteva, Inc.**
Location	Tanner, AL, US
Contact	Eric Linder
510(k) history	11 submissions · 11 cleared · 2019-2026