FDA 510(k) Premarket Notification

CLEARED

K252205 Curiteva Porous PEEK Cervical Interbody System

Jan 16, 2026
186 days to decision

K252205 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k252205/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jul 14, 2025
Decision date	Jan 16, 2026
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Curiteva Porous PEEK Lumbar Interbody System; Curiteva Porous PEEK Laminoplasty System; Curiteva Porous PEEK Standalone ALIF System

APPLICANT

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