FDA 510(k) Premarket Notification

CLEARED

K213030 Curiteva Porous PEEK Cervical Interbody Fusion System

Feb 13, 2023
510 days to decision

K213030 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k213030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Sep 21, 2021
Decision date	Feb 13, 2023
Days to decision	510 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

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Meredith Lee May

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov