FDA 510(k) Premarket Notification

K243137 Curiteva Porous PEEK Laminoplasty System

CLEARED

Oct 28, 2024
28 days to decision

K243137 · Product code: **NQW** · Orthopedic
Source: https://www.510kdatabase.net/k243137/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spine, Plate, Laminoplasty, Metal (NQW)
Date received	Sep 30, 2024
Decision date	Oct 28, 2024
Days to decision	28 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