CLEARED

K250987 aprevo® posterior/transforaminal lumbar interbody fusion device

Jun 30, 2025
91 days to decision

K250987 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k250987/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 31, 2025
Decision date	Jun 30, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Carlsmed, Inc.**
Location	La Jolla, CA, US
Contact	Jesse Albright
510(k) history	20 submissions · 20 cleared · 2020-2026