CLEARED

K241332 aprevo® anterior and lateral lumbar interbody fusion device

Sep 20, 2024
133 days to decision

K241332 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k241332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 10, 2024
Decision date	Sep 20, 2024
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	aprevo® anterior lumbar interbody fusion devices with interfixation; aprevo® transforaminal lumbar interbody fusion device

APPLICANT

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