FDA 510(k) Premarket Notification

CLEARED

K241328 aprevo® Anterior and Lateral Lumbar Interbody Fusion device (ALIF/LLIF)

Aug 12, 2024
94 days to decision

K241328 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k241328/

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	Aug 12, 2024
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	aprevo® Transforaminal Lumbar Interbody Fusion device (TLIF); aprevo® Anterior Lumbar Interbody Fusion device with Interfixation (ALIF-X)

APPLICANT

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