FDA 510(k) Premarket Notification

CLEARED

K222082 aprevo® anterior and lateral lumbar interbody fusion devices, aprevo® transforaminal lumbar interbody fusion devices

Aug 12, 2022
28 days to decision

K222082 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k222082/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 15, 2022
Decision date	Aug 12, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

Carlsmed, Inc. is a medical technology company pioneering personalized spine surgery solutions. The company develops the aprevo® platform, an end-to-end system for patient-specific spinal implants and surgical planning. Carlsmed operates with a manufacturing facility in La Jolla, California. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2020. Orthopedic devices represent the dominant focus, comprising approximately 85% of submissions. Recent clearances span Orthopedic spinal fusion systems for cervical and lumbar indica...