FDA 510(k) Premarket Notification

CLEARED

K260385 aprevo® anterior and lateral lumbar interbody system

May 9, 2026
92 days to decision

K260385 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k260385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 6, 2026
Decision date	May 9, 2026
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	aprevo® posterior and transforaminal lumbar interbody system; aprevo® cervical interbody system; corra™ cervical plating system

APPLICANT

Company	**Carlsmed, Inc.**
Location	La Jolla, CA, US
Contact	Stephanie Crossman
Website	https://carlsmed.com
510(k) history	21 submissions · 21 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...