

K210542 aprevo Transforaminal IBFJun 30, 2021
126 days to decisionK210542 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k210542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 24, 2021
Decision date	Jun 30, 2021
Days to decision	126 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...