FDA 510(k) Premarket Notification

CLEARED

K202034 aprevo Intervertebral Body Fusion Device

Dec 3, 2020
133 days to decision

K202034 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k202034/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 23, 2020
Decision date	Dec 3, 2020
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Carlsmed, Inc.**
Location	La Jolla, CA, US
Contact	Mike Cordonnier
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...