

K222195 aprevo® Digital WorkflowDec 30, 2022
161 days to decisionK222195 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k222195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 22, 2022
Decision date	Dec 30, 2022
Days to decision	161 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...