

**K211987 ATEC Alignment App**Oct 29, 2021  
123 days to decisionK211987 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k211987/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 28, 2021
Decision date	Oct 29, 2021
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Alphatec Spine, Inc.</b>
Location	Carlsbad, CA, US
Contact	David Gramse
Website	<a href="https://www.alphatecspine.com">https://www.alphatecspine.com</a>
510(k) history	93 submissions · 93 cleared · 2005-2026

Alphatec Spine, Inc. is a spine surgery medical device company based in Carlsbad, California. The company develops and markets surgical solutions for spinal fusion and fixation procedures. Alphatec Spine maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. The company specializes in Orthopedic devices, which represent 91% of its submission portfolio. Clearances span from 2005 to 2026, demonstrating sustained regulatory activity and recent market engagement. Recent cleared devices include robotic navigation systems, interbody s...