

**K090782 NOVEL ALIF SPINAL SPACER SYSTEM**Apr 22, 2009  
30 days to decisionK090782 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k090782/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 23, 2009
Decision date	Apr 22, 2009
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alphatec Spine, Inc.</b>
Location	Carlsbad, CA, US
Contact	MARY STANNERS
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...

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