

**K211873 PSX Interbody System**Aug 10, 2021  
54 days to decisionK211873 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k211873/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 17, 2021
Decision date	Aug 10, 2021
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alphatec Spine, Inc.</b>
Location	Carlsbad, CA, US
Contact	Cynthia Dorne
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...