

**K240199 IntraOp Alignment System**May 22, 2024  
118 days to decisionK240199 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k240199/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jan 25, 2024
Decision date	May 22, 2024
Days to decision	118 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	Unnati Bhuptani
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...