

K253216 IntraOp Alignment SystemJun 25, 2026
269 days to decisionK253216 · Product code: **SIN** · Radiology
Source: <https://www.510kdatabase.net/k253216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Sep 29, 2025
Decision date	Jun 25, 2026
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary
Other names	CONTOUR3D Bending System

APPLICANT

Company	Alphatec Spine, Inc.
Location	Carlsbad, CA, US
Contact	Unnati Bhuptani
Website	https://www.alphatecspine.com
510(k) history	94 submissions · 94 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...
