FDA 510(k) Premarket Notification

CLEARED

K232345 ATEC Posterior Navigated Disc Prep Instruments

Nov 2, 2023
90 days to decision

K232345 · Product code: **OLO** · Orthopedic
Source: https://www.510kdatabase.net/k232345/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Stereotaxic Instrument (OLO)
Date received	Aug 4, 2023
Decision date	Nov 2, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Alphatec Spine, Inc.**
Location	Carlsbad, CA, US
Contact	Sandy Gill
Website	https://www.alphatecspine.com
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...