FDA 510(k) Premarket Notification

CLEARED

K103205 BRIDGEPOINT SPINOUS PROCESS CAMP-POSTERIOR FIXATION SYSTEM

Jun 2, 2011
213 days to decision

K103205 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k103205/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Nov 1, 2010
Decision date	Jun 2, 2011
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Alphatec Spine, Inc.**
Location	Carlsbad, CA, US
Contact	OLGA LEWIS
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...