FDA 510(k) Premarket Notification

K081730 NOVEL CERVICAL SPINAL SPACER SYSTEM

CLEARED

Sep 19, 2008
93 days to decision

K081730 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k081730/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jun 18, 2008
Decision date	Sep 19, 2008
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Alphatec Spine, Inc.**
Location	Carlsbad, CA, US
Contact	MARY SCANNERS
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...