FDA 510(k) Premarket Notification

K111634 XENON(TM) PEDICLE SCREW SYSTEM

CLEARED

Jan 25, 2012
226 days to decision

K111634 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k111634/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 13, 2011
Decision date	Jan 25, 2012
Days to decision	226 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Alphatec Spine, Inc.**
Location	Carlsbad, CA, US
Contact	CHERYL ALLEN
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...