FDA 510(k) Premarket Notification

K181980 OsseoScrew System

CLEARED

Sep 25, 2018
62 days to decision

K181980 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k181980/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 25, 2018
Decision date	Sep 25, 2018
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Alphatec Spine, Inc.**
Location	Carlsbad, CA, US
Contact	Jeremy Markovich
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...