

K181677 Kodiak Spinal Fixation System

Aug 9, 2018
44 days to decisionK181677 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k181677/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 26, 2018
Decision date	Aug 9, 2018
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alphatec Spine, Inc.
Location	Carlsbad, CA, US
Contact	Cynthia Adams
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...

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