FDA 510(k) Premarket Notification

CLEARED

K261284 Invictus® Small Stature Spinal Fixation System

Jul 14, 2026
88 days to decision

K261284 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k261284/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Apr 17, 2026
Decision date	Jul 14, 2026
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Invictus® 2.0 Spinal Fixation System

APPLICANT

Company	**Alphatec Spine, Inc.**
Location	Carlsbad, CA, US
Contact	Andrew Zhang
Website	https://www.alphatecspine.com
510(k) history	95 submissions · 95 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...