

K232173 Ascend VBR System, Ascend NanoTec VBR SystemOct 6, 2023
77 days to decisionK232173 · Product code: **MQP** · Orthopedic
Source: <https://www.510kdatabase.net/k232173/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinal Vertebral Body Replacement Device (MQP)
Date received	Jul 21, 2023
Decision date	Oct 6, 2023
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alphatec Spine, Inc.
Location	Carlsbad, CA, US
Contact	Sandy Gill
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...