

K234092 SafeOp 3: Neural Informatix SystemApr 19, 2024
115 days to decisionK234092 · Product code: **GWF** · Neurology
Source: <https://www.510kdatabase.net/k234092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Dec 26, 2023
Decision date	Apr 19, 2024
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alphatec Spine, Inc.
Location	Carlsbad, CA, US
Contact	Unnati Bhuptani
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...