

K093077 ZODIAC POLYAXIAL SPINAL FIXATION SYSTEMDec 23, 2009
84 days to decisionK093077 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k093077/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Orthosis, Spinal Pedicle Fixation (MNI) |
| Date received | Sep 30, 2009 |
| Decision date | Dec 23, 2009 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Alphatec Spine, Inc. |
| Location | Carlsbad, CA, US |
| Contact | CHERYL ALLEN |
| 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...
