FDA 510(k) Premarket Notification

# K253169 Duet™ Spinal Fixation System

**CLEARED**

Feb 23, 2026
150 days to decision

K253169 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k253169/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received | Sep 26, 2025 |
| Decision date | Feb 23, 2026 |
| Days to decision | 150 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Box Spine, LLC** |
| Location | Tulsa, OK, US |
| Contact | Troy Walters |
| Website | https://boxspine.com |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

Box Spine, LLC designs and manufactures pre-sterilized spinal implants and surgical instruments for ambulatory surgery centers. The company specializes in single-use, ready-to-use surgical kits that simplify spinal fusion procedures in the ASC setting. Box Spine operates with a manufacturing facility in Tulsa, Oklahoma. The company has received FDA 510(k) clearance from total submission. Box Spine focuses exclusively on Orthopedic devices, with its flagship product being the Duet™ Spinal Fixation System. The company achieved its first clearance in 2026 and remains activel...

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Applied Technical Services (Empirical Technologies)** |
| Contact | Hannah Taggart |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov