FDA 510(k) Premarket Notification

# K232457 Q-FIX ULTRA All-Suture Anchor

**CLEARED**

Sep 8, 2023
25 days to decision

K232457 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k232457/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received | Aug 14, 2023 |
| Decision date | Sep 8, 2023 |
| Days to decision | 25 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Smith & Nephew** |
| Location | Memphis, TN, US |
| Contact | Catherine Phelan |
| Website | http://www.smith-nephew.com/ |
| 510(k) history | 17 submissions · 17 cleared · 2015-2025 |

Smith & Nephew is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in Memphis, US, and serves approximately 100 countries worldwide. The company has received FDA 510(k) clearances from total submissions since 2015. Orthopedic devices represent the dominant category, including pelvic and acetabular systems, patella plates, suture anchors, cable systems, external fixators, arthroscopes, and limb lengthening systems. The latest clearance was granted in 2025, confirming a...