

**K241435 Q-FIX Knotless All-Suture Anchor, 1.8 mm, with one ULTRABRAID suture, blue**Jun 20, 2024  
30 days to decisionK241435 · Product code: MBI · Orthopedic  
Source: <https://www.510kdatabase.net/k241435/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	May 21, 2024
Decision date	Jun 20, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Q-FIX Knotless All-Suture Anchor, 1.8 mm, with one ULTRABRAID suture, co-braid-blue; Q-FIX Knotless All-Suture Anchor, 1.8 mm, with one MINITAPE suture, blue; Q-FIX Knotless All-Suture Anchor, 1.8 mm, with one MINITAPE suture, co-braid-blue

**APPLICANT**

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Company	<b>Smith &amp; Nephew, Inc.</b>
Location	Mchenry, IL, US
Contact	Rebecca Peterkins
Website	<a href="http://www.smith-nephew.com/">http://www.smith-nephew.com/</a>
510(k) history	530 submissions · 517 cleared · 1980-2026

Smith & Nephew, Inc. is a medical technology company focused on repair, regeneration, and replacement of soft and hard tissues. The company operates with a manufacturing facility in McHenry, US. Smith & Nephew has established a significant regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since 1980. Orthopedic devices represent the dominant category, accounting for 71% of submissions. The company remains active, with the latest clearance in 2025. Recent cleared devices reflect a strong focus on orthopedic surgical...