

K261968 Q-FIX KNOTLESS All-Suture Anchor, 2.8mm, with one black knotless and one blue MINITAPE suture (72205981)

Jul 9, 2026
28 days to decision

K261968 · Product code: MBI · Orthopedic
Source: <https://www.510kdatabase.net/k261968/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Jun 11, 2026
Decision date	Jul 9, 2026
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Q-FIX KNOTLESS All-Suture Anchor, 2.8mm, with one blue knotless and one black MINITAPE suture (72205982)

APPLICANT

Company	Smith & Nephew, Inc.
Location	Mchenry, IL, US
Contact	Xianjun Chen
Website	http://www.smith-nephew.com/
510(k) history	532 submissions · 518 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...