FDA 510(k) Premarket Notification

K252635 ArthroTAK Tendon Anchor Kit

CLEARED

May 1, 2026
254 days to decision

K252635 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k252635/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Aug 20, 2025
Decision date	May 1, 2026
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**ArthroTAK, LLC**
Location	Missoula, MT, US
Contact	Don Running
Website	https://arthrotak.com
510(k) history	1 submissions · 1 cleared · 2026-2026

ArthroTAK, LLC develops sutureless tendon-to-bone fixation technology for orthopedic surgery. The company specializes in simplifying biceps tenodesis and related procedures through innovative fixation devices. ArthroTAK operates with a manufacturing facility in Missoula, US. The company has received FDA 510(k) clearance from total submission. ArthroTAK's focus is Orthopedic devices, representing 100% of its regulatory submissions. The company achieved its first and latest clearance in 2026, demonstrating active regulatory engagement. ArthroTAK's cleared device addresses c...

REGULATORY CONSULTANT

Consulting firm	**RPC Consulting, LLC**
Contact	Ken Riordan

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