FDA 510(k) Premarket Notification

CLEARED

K243344 Arthrex FiberTape and TigerTape Cerclage Sutures

Feb 20, 2025
118 days to decision

K243344 · Product code: **JDQ** · Orthopedic
Source: https://www.510kdatabase.net/k243344/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	Oct 25, 2024
Decision date	Feb 20, 2025
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Arthrex Radiopaque FiberTape Cerclage Sutures

APPLICANT

Company	**Arthrex, Inc.**
Location	Naples, FL, US
Contact	Emmarie Halteman
Website	https://www.arthrex.com
510(k) history	346 submissions · 342 cleared · 1992-2026

Arthrex, Inc. is a medical device manufacturer based in Naples, US. The company specializes in surgical implants and instruments for orthopedic procedures. Arthrex has received FDA 510(k) clearances from total submissions since its first clearance in 1992. The company's portfolio is dominated by Orthopedic devices, which represent 89% of its regulatory submissions. Recent cleared devices include suture anchors, plating systems, nails, and specialized fixation devices for shoulder, ankle, and lower extremity procedures. The latest FDA 510(k) clearance was received in 2026,...