

K251690 Arthrex SpeedFLEX™ ImplantSep 30, 2025
120 days to decisionK251690 · Product code: **OWY** · Orthopedic
Source: <https://www.510kdatabase.net/k251690/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement Of Tendon (OWY)
Date received	Jun 2, 2025
Decision date	Sep 30, 2025
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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,...