FDA 510(k) Premarket Notification

K220880 Arthrex BioSuture

CLEARED

Oct 27, 2022
216 days to decision

K220880 · Product code: **GAT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Mar 25, 2022
Decision date	Oct 27, 2022
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Arthrex, Inc.**
Location	Naples, FL, US
Contact	Stacy Valdez
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,...