FDA 510(k) Premarket Notification

K071622 ARTHREX FIBERWIRE

CLEARED

Jul 3, 2007
19 days to decision

K071622 · Product code: **GAT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k071622/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Jun 14, 2007
Decision date	Jul 3, 2007
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arthrex, Inc.**
Location	Naples, FL, US
Contact	ANN WATERHOUSE
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,...