

**K112040 ARTHREX BIOCOMPOSITE TRANSFIX**Dec 15, 2011  
150 days to decisionK112040 · Product code: **MAI** · Orthopedic  
Source: <https://www.510kdatabase.net/k112040/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Jul 18, 2011
Decision date	Dec 15, 2011
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Arthrex, Inc.</b>
Location	Naples, FL, US
Contact	SALLY FOUST
Website	<a href="https://www.arthrex.com">https://www.arthrex.com</a>
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,...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112040/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 15, 2026