

**K943492 ARTHREX STAPLES**Feb 1, 1995  
197 days to decisionK943492 · Product code: **JDR** · Orthopedic  
Source: <https://www.510kdatabase.net/k943492/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Jul 19, 1994
Decision date	Feb 1, 1995
Days to decision	197 days
Third-party review	No

**APPLICANT**

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Company	<b>Arthrex, Inc.</b>
Location	Naples, FL, US
Contact	LEONARD E BALTZ
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,...

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