

K230513 Arthrex Univers Apex OptiFit Humeral StemSep 26, 2023
214 days to decisionK230513 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k230513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Feb 24, 2023
Decision date	Sep 26, 2023
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arthrex, Inc.
Location	Naples, FL, US
Contact	Tiffany Mentzel
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,...

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Device record: <https://www.510kdatabase.net/k230513/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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