

K260624 Arthrex Radial Head Replacement System

Jul 30, 2026
154 days to decision

K260624 · Product code: **KWI** · Orthopedic
Source: <https://www.510kdatabase.net/k260624/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Feb 26, 2026
Decision date	Jul 30, 2026
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arthrex, Inc.
Location	Naples, FL, US
Contact	Rebecca Homan
Website	https://www.arthrex.com
510(k) history	351 submissions · 347 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

Device record: <https://www.510kdatabase.net/k260624/> Data sourced from FDA 510(k) public records (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. - Generated August 12, 2026