FDA 510(k) Premarket Notification

CLEARED

K221232 Univers Revers Humeral Cup Implant

May 19, 2022
20 days to decision

K221232 · Product code: **HSD** · Orthopedic
Source: https://www.510kdatabase.net/k221232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (HSD)
Date received	Apr 29, 2022
Decision date	May 19, 2022
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Arthrex, Inc.**
Location	Naples, FL, US
Contact	Ivette Galmez
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,...