FDA 510(k) Premarket Notification

K071032 ARTHREX UNIVERS II SHOULDER PROSTHESIS

CLEARED

Aug 20, 2007
131 days to decision

K071032 · Product code: **KWS** · Orthopedic
Source: https://www.510kdatabase.net/k071032/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Apr 11, 2007
Decision date	Aug 20, 2007
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arthrex, Inc.**
Location	Naples, FL, US
Contact	NANCY HOFT
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,...