FDA 510(k) Premarket Notification

CLEARED

K182039 Arthrex Univers Revers Porous Coated Baseplate and Universal Glenoid Inlay

Sep 28, 2018
60 days to decision

K182039 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k182039/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Jul 30, 2018
Decision date	Sep 28, 2018
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arthrex, Inc.**
Location	Naples, FL, US
Contact	Courtney Smith
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,...