

K212415 Arthrex Modular Glenoid System-Titanium Glenosphere

Nov 17, 2021
106 days to decisionK212415 · Product code: PHX · Orthopedic
Source: <https://www.510kdatabase.net/k212415/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Aug 3, 2021
Decision date	Nov 17, 2021
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Arthrex, Inc.
Location	Naples, FL, US
Contact	David L. Rogers
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,...