FDA 510(k) Premarket Notification

CLEARED

K160461 Arthrex iBalance BiCompartmental Arthroplasty System

Apr 12, 2016
53 days to decision

K160461 · Product code: **KRR** · Orthopedic
Source: https://www.510kdatabase.net/k160461/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femoral, Semi-constrained, Cemented, Metal/polymer (KRR)
Date received	Feb 19, 2016
Decision date	Apr 12, 2016
Days to decision	53 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,...