

**K153115 Arthrex Univers Apex, Size 5 Stem**Nov 23, 2015  
26 days to decisionK153115 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k153115/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Oct 28, 2015
Decision date	Nov 23, 2015
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Arthrex, Inc.</b>
Location	Naples, FL, US
Contact	COURTNEY SMITH
Website	<a href="https://www.arthrex.com">https://www.arthrex.com</a>
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,...

---