

## K260353 Arthrex Humeral Plating System (Anatomic Humeral Plate) and Cerclage Button

Mar 3, 2026  
28 days to decisionK260353 · Product code: HRS · Orthopedic  
Source: <https://www.510kdatabase.net/k260353/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 3, 2026
Decision date	Mar 3, 2026
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Arthrex, Inc.</b>
Location	Naples, FL, US
Contact	Osiris Rios
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,...