

**K190953 Arthrex Minimally Invasive Ankle Fusion Plate**Oct 16, 2019  
188 days to decisionK190953 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k190953/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 11, 2019
Decision date	Oct 16, 2019
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arthrex, Inc.</b>
Location	Naples, FL, US
Contact	Caroline Bloemker
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,...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190953/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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