

**K202912 ARIX Ankle Distal Tibia System**Oct 29, 2020  
30 days to decisionK202912 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k202912/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 29, 2020
Decision date	Oct 29, 2020
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Jeil Medical Corporation</b>
Location	Deer Field, IL, US
Contact	Ahhyeon Woo
510(k) history	53 submissions · 53 cleared · 2002-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202912/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 15, 2026