

K170313 ARIX Ankle Distal Tibia SystemJul 27, 2017
176 days to decisionK170313 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k170313/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 1, 2017
Decision date	Jul 27, 2017
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jeil Medical Corporation
Location	Deer Field, IL, US
Contact	Sejin RYU
510(k) history	53 submissions · 53 cleared · 2002-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170313/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026