

K231887 ARIX Ankle Distal Tibia SystemDec 14, 2023
170 days to decisionK231887 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k231887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jun 27, 2023
Decision date	Dec 14, 2023
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231887/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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