

K231441 ARIX Ankle SystemJul 17, 2023
60 days to decisionK231441 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k231441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 18, 2023
Decision date	Jul 17, 2023
Days to decision	60 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/k231441/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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