FDA 510(k) Premarket Notification

K230938 ARIX Humerus System

CLEARED

May 3, 2023
30 days to decision

K230938 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k230938/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 3, 2023
Decision date	May 3, 2023
Days to decision	30 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	Bora Kim
510(k) history	53 submissions · 53 cleared · 2002-2026