FDA 510(k) Premarket Notification

K201656 ARIX Elbow System

CLEARED

Sep 15, 2020
89 days to decision

K201656 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k201656/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jun 18, 2020
Decision date	Sep 15, 2020
Days to decision	89 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.net
Device record: https://www.510kdatabase.net/k201656/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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