

**K180972 ARIX Clavicle System**Oct 3, 2018  
173 days to decisionK180972 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k180972/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 13, 2018
Decision date	Oct 3, 2018
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180972/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 16, 2026