

**K172688 Align Radial Head System**Dec 22, 2017  
107 days to decisionK172688 · Product code: **KWI** · Orthopedic  
Source: <https://www.510kdatabase.net/k172688/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Sep 6, 2017
Decision date	Dec 22, 2017
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Skeletal Dynamics, LLC</b>
Location	Shelton, CT, US
Contact	Ana M. Escagedo
510(k) history	18 submissions · 18 cleared · 2010-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172688/> 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 June 20, 2026